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THE GENETIC INFORMATION NONDISCRIMINATION ACT

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON ENERGY AND COMMERCE
HOUSE OF REPRESENTATIVES

ONE HUNDRED TENTH CONGRESS

FIRST SESSION

ON

H.R. 493

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H.R. 493, THE GENETIC INFORMATION NONDISCRIMINATION ACT

THURSDAY, MARCH 8, 2007

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON HEALTH,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC.

The subcommittee met, pursuant to call, at 1:00 p.m., in room 2123 of the Rayburn House Office Building, Hon. Frank Pallone, Jr. (chairman of the subcommittee) presiding.

Members present: Representatives Gordon, Eshoo, Green, DeGette, Capps, Baldwin, Engel, Schakowsky, Solis, Hooley, Deal, Cubin, Wilson, Pitts, Rogers, Myrick, Murphy, and Burgess.

Staff present: John Ford, Jessica McNiece, Jesse Levine, Jonathan Brater, Ryan Long, Nandan Kenkeremath, and Chad Grant.

OPENING STATEMENT OF HON. FRANK PALLONE, JR., A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY

Mr. PALLONE. I am calling the meeting to order and today we are having a hearing on H.R. 493, the Genetic Information Nondiscrimination Act of 2007. The bill would prevent the use of an individual's genetic information from being used to discriminate against them in obtaining health insurance coverage in the workplace.

As science continues to make rapid advancements in the area of genetics, I can't stress how important this bill is to every American citizen. Genetic testing has increasingly become an integral part of the American healthcare system, providing the possibility to develop better therapies that are more effective against disease and allow individuals to take steps to reduce the likelihood that they will contract a particular disorder.

However, along with the increasing prevalence of genetic testing comes the growing fear of the potential misuse of this information by way of discrimination in health insurance and employment. For example, people known to carry a gene that may increase the likelihood of cancer may be denied health insurance coverage, since insurers have an incentive to identify and avoid beneficiaries who will cost them more money than the average beneficiary.

Furthermore, many genetic conditions and disorders are associated with particular racial and ethnic groups and therefore members of a particular group may be stigmatized or discriminated against as a result of their genetic information. There have been several documented cases of genetic discrimination carried out by

both insurers and employers. A 2001 American Management Association survey of U.S. companies found that a number of employers were conducting tests that employers acknowledge might include genetic testing, as well as requesting employees' family medical histories.

And the fear of genetic discrimination alone can have significant societal cause. For example, many Americans may be reluctant to undergo genetic testing because of such fear, thereby hindering essential genetic research and clinical practices. Many people may be deterred to participate in biomedical research that studies gene mutations associated with certain disease because of the fear that their information could be used against them by insurers and employers.

And even more alarming, patients who could benefit from genetic testing have often avoided testing out of concern for possible repercussions, therefore losing the opportunity to received monitoring and preventive care for conditions in which they are at a higher risk.

A 2004 Genetics and Public Policy Center survey showed that 92 percent of respondents thought employers should not have access to their genetic test results and 80 percent opposed letting insurance companies have access to the results. And we think or I should say I believe that current laws need to be strengthened to protect against the possibility of genetic discrimination. While the Health Insurance Portability and Accountability Act of 1996 created Federal protections against genetic discrimination, these protections are limited; I think very limited.

Under HIPAA, Congress established certain restrictions for group health insurance use of health related information in terms of coverage and setting premiums. However, these protections did not apply to individual health insurance nor do they prevent insurers from denying an entire group coverage or setting higher premiums based on the results of genetic testing results from one of its members.

Many States have also enacted genetic nondiscrimination laws, yet these provisions vary widely in their approach, application and degree of protection and therefore I believe that Federal legislation is necessary to establish a national protection against potential genetic discrimination.

As knowledge of the human genome expands, a greater proportion of the population will likely be identified as carriers of mutations associated with a greater risk of certain diseases, indicating that virtually all people are potential victims of genetic discrimination in health insurance. And we need to work in a bipartisan fashion to tackle this issue. I would point out that this legislation does have a lot of Republican, as well as Democratic support. It actually passed the Senate twice, so it does have a lot of support on both sides of the aisle already.

The president, President Bush, has also indicated that he supports the bill, so we have an opportunity to actually pass something here that will also pass the Senate and be signed by the president and that is why I think that it is particularly important that we act swiftly. There is absolutely no reason why we shouldn't work together to pass the bill and get it to the president's desk.

So in closing, I would like to thank the sponsor of this bill. I know Representative Louise Slaughter has been pushing this for as long as I can remember. She talks to me about it all the time and of course, Anna Eshoo, the member of this committee, who has also been not only a cosponsor, but a leader on this issue. They have done a lot of work to put this bill together over the years and it is immensely important. In my opinion, it holds a lot of promise. So thank you.

I will now recognize our ranking member, Mr. Deal of Georgia.

Mr. DEAL. Thank you, Mr. Chairman. I am going to waive my opening statement, but I would request unanimous consent that all Members be allowed to insert their statements in the record.

[The prepared statement of Mr. Deal follows:]

PREPARED STATEMENT OF HON. NATHAN DEAL, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF GEORGIA

Mr. Chairman, I want to thank you for holding this hearing today on H.R. 493, the Genetic Information Nondiscrimination Act. I realize the Committee has limited time to act on this possibly far reaching legislation but I am glad we are taking this opportunity to hear about the impact of this bill.

My primary concerns with this legislation are the definitions of "genetic test" and "genetic information". I fear these definitions are so broad that routine medical tests and information may be covered by this bill. Many States including my own have enacted their own genetic nondiscrimination legislation which include specific exclusions we do not find in H.R. 493. In Georgia's law, the definition of genetic testing focuses on tests for the purpose of identifying the presence or absence of inherited alterations in genetic material which are associated with a disease that arises solely as a result of the abnormality in the genes. It also includes specific exceptions for routine physical measurements; chemical, blood, and urine analysis; tests for abuse of drugs; and tests for the presence of the human immunodeficiency virus (HIV). Yet, the definition of a genetic test we find in this bill goes so far as to include an analysis which simply detects genotypes. Nor do we find clear exceptions for routine tests or for the abuse of drugs. This broad drafting leaves open the possibility that tests the authors of this legislation may have never intended to cover being included in this bill.

I am also concerned with how this legislation may interact with the action 43 States have already taken on this issue. It seems that in this bill, we would be legislating in a sweeping manner; in an area the vast majority of the states have already taken action. This could lead to a great deal of confusion in the states about which regulations actually apply. I believe this bill uses a standard of stringency to determine which regulation, the State or Federal, should apply. Without a clear determination, this could make it difficult for employers and insurers to comply with this bill.

I realize many of our witnesses today will testify about the need for this legislation to allay the public's fears of being genetically tested and the important role genetic information may play in the delivery of health care in the future. I hope the witnesses could also help guide the Committee to act in a specific way that would limit the bill's unintended consequences in the future.

Again, I am glad we are taking this opportunity today and I hope our witnesses will be able to address some of my concerns and indicate the implications of this important legislation.

Mr. PALLONE. Thank you, Mr. Deal. I next would recognize Ms. Eshoo, who is the chief proponent of this legislation.

OPENING STATEMENT OF HON. ANNA G. ESHOO, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Mr. ESHOO. Thank you, Mr. Chairman, for having this legislative hearing. It has been a long time in coming. I think this is a very important and auspicious moment for the issue at hand and that

is as the great discovery, I think the greatest discovery of the 20th century, just before we started the 21st century, was the mapping of the human genome project. But with that discovery came another one and that is that the wonder and the manifestation of what that promise held would be withheld because of the fear of being discriminated against, and that is why we are here today.

I want to salute our colleagues, Congresswomen Louise Slaughter and Judy Biggert, who have done a superb job on this. I am proud to have played a role to help to build the coalition of very, very important national organizations; some may be unlikely partners, but that makes the case even stronger for us to pass the bill. And with Dr. Collins here today, I think you will remember when I was the co-chair of one of the bipartisan retreats and of course, the Speaker of the House was there, as well as the minority leader, and I believe it was Speaker Hastert and Minority Leader Gephardt.

And they were sitting at tables next to each other, not together, which is not atypical, right? But Dr. Collins and I were sitting together and he was a guest; he had been invited to come to the retreat to be instructive to all of the members about the challenge that was before us. And I said to Dr. Collins you must go up to the Speaker and the minority leader. I will try to get them to stand next to you together so that you can address them together and challenge them to take a hold of this and make sure that it happened.

Well, that was some time ago and although it didn't happen then, we have been helping to make it happen and I am very excited that we are on the threshold of this and that we will work through the bill. If there are ways to improve it, we look forward to that. If there are ways that will essentially kill it, I think that there are enough of us that won't allow that to happen. I think the people in the country deserve a very good bill in this area and I think that when this committee passes it, we will have distinguished ourselves in a very important way.

So thank you, Mr. Chairman. Thank you, Dr. Collins, for all that you have done, and to the witnesses that are here today to talk about the bill and answer the important questions that members from both sides of the aisle will pose. Thank you.

Mr. PALLONE. Thank you. And thank you for all the work you have done over the past few years in trying to move this. I recognize the gentleman from Michigan, Mr. Rogers.

Mr. ROGERS. I will waive for more questioning time, Mr. Chairman.

Mr. PALLONE. And next we have our vice chair, the gentleman from Texas, Mr. Green.

OPENING STATEMENT OF HON. GENE GREEN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr. GREEN. Thank you, Mr. Chairman, for one, holding this hearing and also, as vice chair, I would like to welcome our witnesses to the subcommittee and my colleague from California, thank you for your efforts for many years. Some of us have been cosponsors of this for six terms, it seems like. One of our subcommittee's important responsibility is protecting the rights of pa-

tients for their confidentiality and I hope we can address this important issue in a bipartisan and cooperative way.

Our society supports the idea that a person should be hired based on their qualifications and ability to perform the job, instead of characteristics out of their control, which have no effect on their job performance. Racial, gender and other types of discrimination is incompatible with merit-based economic systems that rewards people for work and effort. Discrimination based on health conditions is also incompatible with our society and economy, so people should not be fired because of their family history of a certain illness.

There should also be a consensus that people should not be charged a higher price for health insurance based on their family's medical history. The recent advances in the field of human genetics has brought these issues to the forefront because as usual, new technologies bring new benefits but also, new opportunities for harm. Genetic testing is proven to be extremely helpful in preventative medicine. It allows for individuals with risk of an illness to take the precautionary steps ahead of time, which will help keep healthcare costs to the minimum.

It is important that we continue to support genetic testing in order to further scientific advancement while protecting Americans from any negative impact due to their participation. There are over 15,500 recognized genetic disorders which affect millions of Americans. It would be unfair to penalize someone based on their genes by using this information improperly. Under most circumstances, a person should be allowed to refuse a genetic test without fear of being fired.

Also, if an individual is taking a genetic test, the test should be conducted in terms which they agree and the results should be released only if on the consent of that individual. These issues are properly addressed in H.R. 493, which again, I co-sponsored along with many supporters in the House. I believe President Bush has made it evident he will also support these principles. This hearing is an excellent opportunity for our committee to work together to protect Americans from this discrimination based on health concerns. And I yield back the balance of my time.

Mr. PALLONE. Thank you. Dr. Burgess is recognized for an opening.

Mr. BURGESS. Thank you, Mr. Chairman. Thank you for calling this hearing. In deference to the quality of witnesses we have today, I will just submit for the record.

Mr. PALLONE. You are reserving your time for questions, OK. The gentlewoman from Colorado, Ms. DeGette.

Ms. DEGETTE. Thank you, Mr. Chairman. As usual, Mr. Green said it all and better than I could have, so I will waive my opening statement.

Mr. PALLONE. Mr. Pitts.

Mr. PITTS. I will waive.

Mr. PALLONE. The gentlewoman from Wisconsin, Ms. Baldwin.

OPENING STATEMENT OF HON. TAMMY BALDWIN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF WISCONSIN

Ms. BALDWIN. Thank you, Mr. Chairman, and thank you to our witnesses today. I am truly delighted that this subcommittee is taking up this very important bill. It is clear that the time has come to extend nondiscrimination protections to include genetic information. This particular issue, genetic information discrimination, poses a unique challenge for us, but I think we are up to the task. The scientific advancement that has been made in sequencing the human genome is groundbreaking and I am excited that the leading scientist involved with the Human Genome Project is here today, as you have been in the past at our bipartisan conference that I also had a chance to attend. I am glad you are here today to share your expertise with us.

We have only just begun to understand how we can harness the vast amount of information that is included in the genetic code to benefit human health and longevity. We have yet to see the limits of the ways that this information can benefit all of us. The ability to predict disease will greatly increase our opportunities for early treatment and prevention efforts and this can have a real impact on people's lives.

So we must not allow discrimination to prevent us from taking full advantage of the important opportunities that genetic information provides. We need to provide strong protections that will prevent employers and insurers from denying health coverage or job opportunities on the basis of predictive genetic information. This important protection is necessitated by these incredible advancements in the science and we, members of Congress, are responsible for making sure that our laws keep up with these scientific advancements so that we can fully realize the value of these discoveries.

I am proud to be an original cosponsor of this legislation and I look forward to seeing these important protections extended to all Americans. Thank you, Mr. Chairman.

Mr. PALLONE. Thank you. Mrs. Capps has returned, so I will recognize her.

OPENING STATEMENT OF LOIS CAPPS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Mrs. CAPPS. I apologize. I did not want to miss this very special moment. Thank you, Mr. Chairman, for holding this hearing. I want to acknowledge my colleague, Anna Eshoo, and her partners, Louise Slaughter and Judy Biggert for their work. There has been a steady push to get to this day. After so many years and it is quite an accomplishment here. And especially with our first witness; well, with all of our witnesses, it will be a remarkable day. To have Dr. Collins here with us today is very auspicious. This is a very appropriate time to have you and all of us remember when he first showed us the charts of the completion of the Genome Project. And now we have today's topic to deal with.

We need this hearing today because we are paving the way for consideration of legislation that, as I said, so many of us strongly support. The identification of genetic markers for disease is one of

the most remarkable scientific accomplishments we have made. With Dr. Collins at the helm, we are going to continue to see even greater accomplishments in our understanding of genetics. As we all know, we can never emphasize enough just how important preventive health care is to our wellbeing. The ability to identify risks for certain conditions promises to enhance our ability to identify and practice greater preventive healthcare in this country.

It is about quality of life, it is about saving life, but at the same time, as with almost all great scientific advancements, we have also opened the door to a whole slew of unintended consequences. I fear that preventive healthcare is being put at risk when patients decline genetic testing for fear of insurance or employment discrimination. I know we will hear from at least one witness today about the juxtaposition of a public that is overwhelmingly optimistic about the benefits of genetic testing, but overwhelmingly pessimistic about their privacy being protected. What a shame.

We need to work together on ways to promote ethical genetic testing with appropriate privacy protections and with measures in place to prevent discrimination. This is our task. I believe we can do it. We cannot continue with a system in place that leaves individuals who might be at risk for a disease to forego available genetic testing for fear of losing their job or their health insurance.

I am proud to be a strong supporter of the Genetic Nondiscrimination Act so that we can ensure that this will not occur in the future. I look forward to hearing from all of you today. Thank you very much for coming. I yield back.

Mr. PALLONE. Thank you. I recognize the gentleman from Pennsylvania, Mr. Murphy.

OPENING STATEMENT OF HON. TIM MURPHY, A REPRESENTATIVE IN CONGRESS FROM THE COMMONWEALTH OF PENNSYLVANIA

Mr. MURPHY. Thank you, Mr. Chairman, and thank you for holding this hearing. This is a very, very important issue that has to be addressed. I commend my colleagues, my friends, for putting forth this bill. It is a very important issue to be dealing with in the area of healthcare and a couple of areas. As it has been stated, we are learning more and more about the genome in the role of genetics and what it can teach us about patients; in particular, as just mentioned by my colleague, the issues of prevention.

I would like to see a day when we recognize that treatments have become so sophisticated for patients that understanding their own genetic makeup, that medications and treatments can be made person-specific and come with much more effective treatment plans, such as cancer and other diseases. However, we do need to protect and make sure that patient does not fear losing their job or losing their insurance because they complied or wanted to have these things done.

I wanted to also make sure, and one of the things I hope that perhaps some of our witnesses will be able to address today at the level of expertise, has to do with electronic medical records, because I want to make sure there is no unintended consequence of this bill that might prevent a business that might try and help its employees by providing electronic medical records to be seen as

somehow gathering information that might be used in some discriminatory manner.

There are so many incredible potentials we have here for healthcare and making it better with prevention and personal specific treatment. I hope we can get to that point and any of the other concerns in this bill, I hope this committee will take care of. And I yield back the balance of my time.

Mr. PALLONE. Thank you. Mr. Engel of New York.

OPENING STATEMENT OF HON. ELLIOT L. ENGEL, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW YOR

Mr. ENGEL. Thank you, Mr. Chairman, for holding this very important hearing on the Genetic Information Nondiscrimination Act. I echo what all of our colleagues said. The sequencing of the human genetic code is unquestionably one of our greatest scientific accomplishments. A researcher's ability to identify genetic markers for diseases has given hope and promise to millions of people regarding how to make more informed choices about their personal healthcare.

The promise of this breakthrough is hindered, though, by well-founded fears of how information may be abused in the employment and insurance industry. In one notable example in 2002, the Burlington-Northern Santa Fe Railway agreed to pay $2.2 million to 36 employees who said the company illegally tested their blood samples to claim a genetic defect that caused their workplace injuries. A study noted by one of our witnesses, Dr. Collins, said that 68 percent of respondents would not bill their insurance company if they chose to have genetic testing done regarding their risk for cancer, colon cancer or breast or ovarian cancer. Twenty-six percent said they wouldn't feel safe getting tested unless they used another name.

A 1998 joint report by the Department of Labor, Equal Employment Opportunity Commission of the Department of Justice stated that Federal legislation was necessary to mandate more appropriate protections against workplace discrimination. While many States, including mine, of New York, have laws which prohibit discrimination in health insurance and by employers based on genetic testing and information, it is clear that they are not fully comprehensive and that Federal action is necessary. Fear should not be a deterrent to knowledge. Disregarding available tests for fear of discrimination prevents citizens from making smarter, personalized choices and being better informed about their own well-being.

Why wait until the standard age that everyone is recommended to start getting mammograms and colonoscopies if one knows he or she is at risk for these diseases? We know too much to subscribe to one-size-fits-all medicine and once again, it should be our physicians, not our insurance companies, who influence our healthcare decisions. I am proud to be an original cosponsor of this bill, it has strong bipartisan support, and the President supports it, as it will clarify how genetic information should be protected in both the insurance and employment setting.

So Mr. Chairman, I thank you again for convening this hearing and I look forward the testimony and this is one thing that is not

political. As Americans, we deserve no less. Thank you. I yield back.

Mr. PALLONE. Thank you. Recognize the gentlewoman from Wyoming, Mrs. Cubin.

OPENING STATEMENT OF HON. BARBARA CUBIN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF WISCONSIN

Mrs. CUBIN. Thank you, Mr. Chairman. The advent of genetic technology holds tremendous promise in the healthcare field. Along with the mapping of the human genome, researchers have identified genes associated with diseases such as Alzheimer's disease, cancer and diabetes. Genetic testing and the information it garners can assess individual predisposition to these debilitating diseases. Continued research may open the door to earlier disease prevention, new diagnostic tools, treatments and potentially, even cures.

Genetic technology could also play a role in making treatment delivery more individualized and effective. As is the case with many rapidly developing technologies, advances in the genetic field are not without their pitfalls. Like a fingerprint, an individual's genetic information serves as a unique personal identifier. The potential misuse of a person's unique genetic information is an important issue to the general public and something that this committee is right to address.

H.R. 493, the Genetic Information Nondiscrimination Act, is intended to prevent discrimination based on genetic information, both in the workplace and in the context of health insurance coverage. As a long time advocate for healthcare privacy, I, too wish to ensure that genetic technology does not become a tool for discrimination or limitation on access to healthcare. H.R. 493's broad definition of genetic information, however, in combination with its sweeping ban on requesting or disclosing genetic information should be looked at critically.

This bill stands to directly impact our Nation's employers, law enforcement and healthcare providers, making it imperative that we root out unintended consequences before we move forward. In the healthcare field in particular, H.R. 493's new regulatory web will have to interlock with the already extensive and complex privacy rules administered by the U.S. Department for Health and Human Services. I am hopeful that our panelists will be able to shed some light on the underlying issues of genetic discrimination, as well as address concerns that this legislation may interfere with the delivery of important and life saving healthcare services.

Thank you, Mr. Chairman. I yield back the balance of my time.

Mr. PALLONE. Thank you. Next is Ms. Solis.

OPENING STATEMENT OF HON. HILDA L. SOLIS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Ms. SOLIS. Thank you, Mr. Chairman, and good afternoon. I want to thank you for holding this very important hearing and I want to just express that I strongly believe that discrimination of any kind, whether it is based on gender, race, disability or genetics, is morally wrong and should not be tolerated. H.R. 493 is critical

in protecting communities that have historically faced discrimination, many of which are at great risk or perceive themselves to be at risk of genetic discrimination.

A study done by Mt. Sinai School of Medicine found that Latino participants believed that there were more disadvantages to genetic testing compared with other ethnic groups and they expressed strong concern regarding testing abuses. Even though African Americans were four times more likely to think that all pregnant women should be genetically tested, a 2006 study published in the Journal of the National Medical Association stated that African Americans were also three times more likely to believe that genetic testing would lead to racial discrimination.

The research participants were concerned that genetic testing results could lead to racially based population control or would block access to health insurance and employment. Unfortunately, these are the same communities which could benefit significantly from genetic testing if only they were protected. Genetic tests can help people determine if someone is at risk of breast, ovarian and other cancers. Breast cancer, as you know, is the leading cause of cancer among Latinos and African American women continue to have higher rates of mortality from breast and cervical cancer.

Native Americans and Alaskan natives continue to have the poorest survival form of all cancers combined than any other racial group. Cancer has been the No. 1 killer of Asian American women since 1980. We need to make sure our residents can access their genetic information without fear that it will be used against them by their insurers or employers. If we do not protect our residents from genetic discrimination, preventable health disparities will continue to increase unnecessarily.

I believe this bill is long overdue and I look forward to hearing from our witnesses today and working with my colleagues to see that this bill moves forward. Yield back the balance of my time.

Mr. PALLONE. Thank you. I recognize the gentlewoman from New Mexico, Mrs. Wilson.

Mrs. WILSON. Thank you, Mr. Chairman. I will waive my opening statement.

Mr. PALLONE. And next is Ms. Hooley, from Oregon.

OPENING STATEMENT OF HON. DARLENE HOOLEY, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF OREGON

Ms. HOOLEY. Thank you, Mr. Chairman. I am proud to say I am a long time supporter of the Genetic Information Nondiscrimination Act. I am hopeful that in the 110th Congress we will finally be able to pass this important piece of legislation. The Health Insurance Portability and Accountability Act of 1996 was a first step in protecting workers from genetic discrimination. However, in the light of the rapid growth in scientific knowledge that has occurred since 1996, it is well past the time that we take strong steps to strengthen genetic nondiscrimination provisions.

Scientific advancements and sequencing the human genome provide exciting opportunities that may allow us to live longer and healthier lives. However, the potential for inappropriate and the discriminatory use of genetic information fosters fear in many people. We will not be able to benefit from the extraordinary scientific

achievements in genetics if people are afraid they will be discriminated against if they undergo genetic testing.

That is why GINA is not only an important privacy and consumer protection bill, but also a bill critical to improve the health of Americans and foster increased scientific research. If people do not trust the way genetic information is used, then the research, itself, will almost certainly be stifled. It would be a tragedy to slow research that holds a potential to provide such tremendous benefit. GINA strikes the appropriate balance between the imperative of protecting the privacy of workers and patients with the need to encourage future scientific advancements.

This legislation will accomplish both sets of goals so that we can feel safe in taking advantage of the improvements in how healthcare is delivered that genetic research allows. I am also encouraged that the president has expressed strong support for genetic nondiscrimination. Hopefully, this time, and I am an optimist, we can get it through the House and the Senate and get it signed by the president. It is the best for the American people. Thank you, Mr. Chairman.

Mr. PALLONE. Thank you. And that concludes the opening statements by members of the subcommittee. Let me just say again that every member has the right to submit their statement for the record.

Let me welcome the panel and mention who we have here. First is Dr. Francis S. Collins, who is director of the National Human Genome Research Institute and the National Institute of Health.

Next is Mr. Kuczynski. He is assistant legal counsel and director of Americans with Disabilities Act Policy Division for the Equal Employment Opportunity Commission. And then we have Ms. Susan McAndrew, who is Deputy Director for Health Information Privacy, Office for Civil Rights, Department of Health and Human Services.

Now, we will have 5-minute opening statements from each of the witnesses. Those statements will be made part of the hearing record. Each witness may, at the discretion of the committee, submit additional briefs and pertinent statements in writing for inclusion in the record. And I will now recognize Mr. Collins to begin with his opening statement. You can proceed.

STATEMENT OF FRANCIS COLLINS, M.D., DIRECTOR, NATIONAL HUMAN GENOME RESEARCH INSTITUTE, NATIONAL INSTITUTES OF HEALTH, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Dr. COLLINS. Thank you, Chairman Pallone, and good afternoon, members of the subcommittee. I am Francis Collins. I am the director of the National Human Genome Research Institute at the National Institutes of Health. I am a physician and a scientist. I want to express my thanks for the opportunity to be here today and my congratulations to this committee for taking on this issue and moving it so quickly in the 110th Congress. Some of us had been waiting a dozen years to get to this point and it is gratifying, indeed, to see this hearing being held this afternoon and to hear these statements of strong support for the principles of the Genetic Information Nondiscrimination Act or GINA, H.R. 493.

We stand on the brink of a revolution in healthcare. The Human Genome Project, which was completed ahead of schedule and under budget in 2003, read out all of the three billion letters of our own human DNA instruction book, providing a foundation for all of the research that we need to do in the future to understand how environment and genetics work together to cause health or disease. In an immediate follow-up at another project that I had the privilege of leading, the International HapMap Consortium, laid out a map of how the variable part of the genome, the 0.1 percent where we differ, is organized across chromosomes and provided with the tools to understand how it is that some of that variation plays a role in risk of disease, be it diabetes, heart disease, Alzheimer's or many other conditions.

We are moving quickly towards the time where your genome might be possible to determine, at high accuracy, for a thousand dollars or less, because the technology is moving so quickly and so there will be a major motivation to make that information a standard part of the medical record. Already, we see around us many gene discoveries happening. More than a thousand genetic tests are now available and discoveries are happening practically every day. Just this week there were discoveries about genetic factors in cleft lip and palate, other genetic factors in Alzheimer's disease, even something about panic disorder. And in the last year we have seen discoveries about macular degeneration, a common cause of blindness, diabetes, prostate cancer, Crone's disease.

NIH has a major investment now in trying to take this opportunity and move it forward at maximum speed so that we can identify other factors that play a role in virtually all hereditary diseases and frankly, all diseases have at least some hereditary contribution. I should say, therefore, personalized medicine, this hope that we can use this information to individualize the way we approach medical problems and focus on keeping people healthy is not for a few people, it is for all us. We all have glitches somewhere in our instruction books that place us at risk for something. The opportunity to discover those and to individualize our individual plans of prevention is one of the major hopes that we have for reducing our healthcare costs and focusing on keeping people healthy.

Yet, there is a cloud on the horizon and it is a cloud that has been getting darker and more frightening over the course of the last more than 12 years, since I have had the privilege of leading the genome effort and worrying about this issue, and that is that this kind of genetic information, as valuable as it is, might be used against people. If I could see the one slide that I brought along, I wanted to put a human face on this particular issue.

[Slide shown.]

So this is a particular family. You can see in the pedigree, that some are drawn as males and some as females. You see a bright red arrow pointing to the woman who first came to attention in one of our research protocols at NIH, and she came to attention because, at the age of 36, she had already had cancer of both the uterus and the colon. And it turned out her mother and her aunt had also had both of those conditions. We recognize that this is a condition that can be strongly inherited. It is called hereditary

nonpolyposis colon cancer and this is one of those conditions for which the genetic basis has been identified.

All of the people that you see in yellow, therefore, are at high risk of having the same condition, but the good news is that knowing you are risk for this condition allows you to undergo medical screening, such as colonoscopy, beginning at an early age; 35 is often recommended. And then one can find the evidences of an early tumor while it is still easily treated, by a surgical procedure. However, in this family, the fear of genetic discrimination made it very difficult for these family members to decide what to do. Ultimately, the woman with the arrow was tested; she was found to have a mutation.

Other family members were offered the chance to find out their status. Her four sisters, as you can see there, given that information, still decided not to be tested because of their fear that this might be used against them. And they are out there somewhere without having life saving information because of this very specific issue, an issue which you all can help us with by getting this legislation passed this year.

This in not a partisan issue, of course. Let me give you one other example. You can take that slide down. Health professionals are not immune to this risk, as well. I am aware of a physician who lives in Chicago who is in a family with a lot of breast cancer. She decided to undergo BRCA1 testing. She decided to do this under a false name because of her concern about this being used against her. What are we doing here? Asking people to use a false name to have a genetic test that might be useful? The test was——

Mr. PALLONE. Dr. Collins, I am going to ask you to summarize, because we do have votes.

Dr. COLLINS. Sure.

Mr. PALLONE. And then I will indicate what we are going to do. If you could wrap up.

Dr. COLLINS. Certainly. Her test was positive. She didn't get that into her medical record. An ultrasound that was done later for another purpose was not looked at carefully because of that consideration. A year later, she was diagnosed with ovarian cancer. It could have been diagnosed if that information had been known.

So let me finish. We remain deeply concerned about the impact of potential genetic discrimination on both research and clinical practice. Unless Americans are convinced this information will not be used against them, this era of personalized medicine may never come to pass. The result will be a continuation of our current one-size-fits-all medicine, ignoring the evidence that genetic differences among people help explain why some of us benefit from a therapy while others do not. This is an issue of equity. It is an issue of justice.

Twenty-four out of the 33 members of this subcommittee are cosponsors of this bill, which I am delighted to note. And the president, in his visit to NIH last month, again called on Congress to pass such a bill, so we are delighted to see this issue being taken up so early in this Congress and are hopeful this will be the year when the American people are given a gift that is long overdue, protection at the Federal legislative level against genetic discrimination.

Thank you, Mr. Chairman. I would pleased to answer any questions.

[The prepared statement of Dr. Collins appears at the conclusion of the hearing.]

Mr. PALLONE. Thank you. Let me explain what we are doing. We have one vote, then we have 10 minutes on the motion to recommit for debate and the we will have three more five-minute votes, so I think, since there is only about 7 or 8 minutes left, we should break now, rather than hear from the next speaker, so figure about, I don't know, half an hour, maybe even 45 minutes. And those are the last votes of the day, so we will break and then we will come back after that. Thank you.

[Recess.]

Mr. PALLONE. The committee will reconvene and we will start where we left off, with Mr. Christopher Kuczynski. I am sorry for the delay, but that is what happens around here. We will have no further delays because we are done voting.

CHRISTOPHER KUCZYNSKI, ASSISTANT LEGAL COUNSEL AND DIRECTOR, AMERICANS WITH DISABILITIES ACT POLICY DIVISION, EQUAL EMPLOYMENT OPPORTUNITY COMMISSION

Mr. KUCZYNSKI. Thank you, Mr. Chairman, and members of the subcommittee. I am pleased to be here today on behalf of Chair Naomi Earp to answer your questions concerning H.R. 493, the Genetic Information Nondiscrimination Act. Since February 1997, I have been Assistant Legal Counsel and Director of the Americans with Disabilities Act Policy Division at the United States Equal Employment Opportunity Commission. In this position, I oversee the development of agency policy on the ADA, counsel EEOC field and headquarters offices that are investigating and litigating ADA charges of discrimination, and provide technical assistance on the law to a wide range of stakeholders.

In the late 1990's, I was part of an inner-agency working group that developed what ultimately became Executive order 13145, which prohibits Federal agencies from discriminating in employment on the basis of protected genetic information, and I provided substantial input on the policy guidance that EEOC issued in July of 2000 to implement that Executive order. Peter Gray, of EEOC's Office of Legal Counsel, who is with me today, also worked on the inter-agency working group that developed the Executive order and was the primary drafter of the EEOC policy guidance on that order.

As this subcommittee is aware, the administration has issued a Statement of Administration Policy supporting Senate passage of a similar bill in the 109th Congress, and former EEOC Chair, Cari Dominguez, on February 13, 2002 expressed this agency's support for legislation prohibiting employment discrimination on the basis of genetic information.

Now basically, my understanding is title II H.R. 493 would do essentially three things. First, with carefully defined exceptions, it would prohibit employers from obtaining genetic information about job applicants and employees that would indicate a predisposition to or increase risk of acquiring a condition in the future. Consistent with limitations that the ADA imposes, employers would still be

permitted to conduct medical examinations of applicants and employees to detect conditions that actually exist and that may affect their ability to perform their jobs.

Second, the bill would prohibit employers from using genetic information indicating that a job applicant or employee has a predisposition to or increased risk of acquiring a condition in the future to deny someone a job or other equal employment opportunities. And in this way, the law is consistent with other laws that the EEOC enforces, such as title VII of the 1964 Civil Rights Act, the Age Discrimination in Employment Act and the ADA, which prohibit discrimination on the basis of some protected status.

Finally, title II of H.R. 493 requires that employers keep genetic information about applicants and employees confidential with limited exceptions. In this respect, the law is similar to the Americans with Disabilities Act, which itself contains confidentiality provisions about medical information that employers acquire.

I know that issues have arisen concerning the relationship of some of H.R. 493's requirements regarding the collection and confidentiality of genetic information to requirements in the Health Insurance Portability and Accountability Act, HIPAA. The EEOC will need to work with the Department of Health and Human Services, the agency responsible for interpreting and implementing HIPAA, assuming that GINA is enacted with current provisions, requiring EEOC to promulgate regulations. We would work closely with other agencies, including the Departments of Labor and the Treasury, who have responsibility for issuing regulations under HIPAA's current nondiscrimination provisions and title I of GINA, as necessary to ensure consistency in the interpretation of terms such as "genetic information" and "genetic tests" that appear in titles I and II. We have well-established procedures for doing this type of coordination.

Additionally, we would have the benefit during the notice and comment period prior to issuance of final regulations, to hear from the public, other Federal agencies, employers and a wide range of stakeholders on the proposed regulations.

Additionally, if EEOC's experience with enforcing and implementing the ADA is any indication, compliance with the requirements of the confidentiality provisions of the GINA should not present insurmountable problems. For example, the ADA allows employers to collect medical information about employees as part of voluntary wellness programs and requires that the information gathered be kept confidential. We have no data to suggest that employers have been deterred from establishing wellness programs because of concerns about the ADA. Indeed, wellness programs seem to be more popular than ever before.

The ADA also allows employers to obtain medical information about applicants and employees in other situations, such as during a medical examination conducted after a job offer has been made, but before employment begins, when an individual with a non-obvious disability requests a reasonable accommodation or when an employer reasonably believes that a current employee's medical condition prevents him or her from performing a job or from performing it safely.

Again, we have not observed that employers are either reluctant to obtain medical information they need or that the applicability of the ADA to some of this information is causing serious compliance problems.

Thank you for the opportunity to appear before you today. I look forward to your questions.

Mr. PALLONE. Thank you, Mr. Kuczynski. Ms. McAndrew.

SUSAN MCANDREW, DEPUTY DIRECTOR FOR HEALTH INFORMATION PRIVACY, OFFICE FOR CIVIL RIGHTS, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Ms. MCANDREW. Thank you, Mr. Chairman and members of the subcommittee. My name is Susan McAndrew. I am the Deputy Director for Health Information Privacy in the Office for Civil Rights in the Department of Health and Human Services and as such, I am responsible for the administration and enforcement of the Privacy Rule that was issued pursuant to the Health Insurance Portability and Accountability Act of 1996. I thank you for this opportunity to testify on the role that the Privacy Rule plays in the protection of genetic information today. I will just start with some brief background material on the Privacy Rule and then turn to the provisions that will be of most interest to this committee.

The Privacy Rule establishes, for the first time, a set of national standards to protect health information, but it is not universally applicable to health information wherever it resides. The standards apply to health information that is individually identifiable and we call that information protected health information. But it only protects that information when it is being held and maintained by what we call covered entities. These entities are health plans, healthcare clearinghouse and those healthcare providers that engage in electronic transactions for which the HIPAA legislation required the Secretary to adopt standards for the electronic exchange of information, most commonly, how they go about billing for their services.

The Privacy Rule protects the information, largely by establishing limitations on how that information is to be used and disclosed, and puts the individual in control to the extent feasible, by requiring that the information only move outside of the entity with the individual's written authorization. The rule does make clear that there are exceptions to when that written authorization is required and these permitted uses and disclosures are largely or primarily focused on the core functions of the health industry that is—the need for this information to treat the patient and to get that treatment paid for in a prompt and accurate manner, as well as to allow healthcare providers and health plans to conduct normal health-related business practices.

There are a limited number of other exceptions that the rule recognizes where public interest may require that this information be disclosed without first obtaining the individual's written authorization. The Privacy Rule also establishes a Federal floor of privacy protections thus allows State and other Federal law to provide more protection as well as business entities to adopt practices that are more protective of privacy

With regard to this legislation, I want to focus on three things. First, individually identifiable genetic information is protected health information under the Privacy Rule today, but we protect this information as we would any other individually identifiable health information. There are no special rules in the Privacy Rule that would add heightened protections because this is genetic information. What the legislation would do, if it is adopted in its current form, would be, for the first time, to introduce a definition of genetic information into the Privacy Rule and apply different protections to this information.

Second, with regard to health plans, currently, the Privacy Rule permits a health plan to use protected health information, and this includes genetic information, for their core business practices; that includes determining enrollment and eligibility for benefits under the plan, as well as underwriting premium rating and the activities related to the creation, renewal or replacement of a contract for insurance. Under this legislation, the health plan would be prohibited from using genetic information for these activities. And the rule also currently allows health plans to condition enrollment or eligibility for benefits under a plan on obtaining an individual's authorization for the release of protected health information if that request is made prior to the enrollment. This is so the plan can get the necessary health information in order to make a determination about enrollment. However, under this legislation, to the extent the information sought pursuant to this type of authorization was genetic information as defined by the bill, that would no longer be permitted.

In addition, for the first time, not only would the bill, title I, make these activities a discriminatory practice for the health plan, similar to what title I of HIPAA does today in some circumstances, but——

Mr. PALLONE. I am just going to ask you to summarize a little, because we are a minute over.

Ms. MCANDREW. OK. I am sorry. The other point that should be made is that the Privacy Rule does not govern a business simply because it is an employer. However, the rule protects the information if the business is involved in healthcare, from flowing from the healthcare side of the business to the employer's side for employment activities that that business would need. And that largely would be the topic of title 2. And I appreciate your having us here today and we look forward to answering your questions.

[The prepared statement of Ms. McAndrew appears at the conclusion of the hearing.]

Mr. PALLONE. Thank you. Thanks a lot. I am going to start by recognizing myself for 5 minutes for questions and I will start with Dr. Collins. I have a couple questions for Dr. Collins.

More than a thousand genetic tests are now available, but most of them are for rare diseases. How rapidly is the science of genetic testing progressing from more common conditions?

Dr. COLLINS. Very rapidly, indeed. With the success of the Human Genome Project, with this follow-after effort called the HapMap Project that has allowed us to really get a sense of a landscape of genetic variation, that 0.1 percent of our DNA where we differ, we now have the tools to be able to scan the entire genome

and identify subtle variations that increase the risk of diseases like diabetes, Alzheimer's disease, prostate cancer, Crohn's disease.

All of the diseases I just mentioned, in fact, have had those discoveries made within the last year and a half and you can anticipate now with these tools in place and with the advances in technology that now make this kind of laboratory work much cheaper than it used to be, you will see a profusion of these discoveries coming out in the course of the next 2 or 3 years. We will discover the major hereditary factors in the common diseases that fill up our hospitals and clinics in the relatively near future.

Mr. PALLONE. So basically, we will see it in the mainstream practice of medicine, would you say?

Dr. COLLINS. We have already seen, in some instances, such as the example of hereditary colon cancer that I presented in my opening statement, an opportunity to integrate this kind of testing for a common disease in a way that saves lives.

Mr. PALLONE. Now, are there any other barriers, though, that would exist for bringing it into the mainstream? Is there anything Congress should be doing to remove barriers or would just move it along fine?

Dr. COLLINS. The main barrier is the one we are here to talk about this afternoon, is this fear of discrimination and which is not an unreasonable fear.

Mr. PALLONE. OK.

Dr. COLLINS. Obviously, we also need to be sure we have supported the medical research to know the answers as crisply as possible so that people who get this information can be given accurate information and that is what NIH and our fellow agencies supporting medical research are committed to doing.

Mr. PALLONE. Let me ask this. I mean, basically, I think you have answered even my second question because you say that doctors are already testing whether some of us carry gene mutation. Well, you stated before that doctors can already test whether some of us carry gene mutations that increase our risk for disease and that more research will expand that capability. But how far can you go with this? Can you offer a guess regarding what proportion of the population would someday be able to learn about their own inherited risk of disease?

Dr. COLLINS. I think ultimately, all of us, because we all carry these risks. Some of us can guess what some of those are from our family history, but not all that accurately. As we learn more and more precisely about the DNA variance that convey those risks, we will be able to offer much more specificity. I would see a time, if this legislation successfully passes and if the research moves at the rate that it seems clearly to do, where each of us, in perhaps as little as 5 years would have the opportunity to find out what our future risks are based on extensive DNA analysis and to be able to alter our lifestyle, our medical surveillance, our diet, our exercise plan to reduce the risks of the things that are highest on our list, instead of doing this in a one-size-fits-all approach, which is our current strategy and which sometimes works and sometimes doesn't.

Mr. PALLONE. And everybody has at least one gene mutation, so everybody is going to be impacted?

Dr. COLLINS. Everybody has dozens of these.

Mr. PALLONE. OK.

Dr. COLLINS. There are no perfect specimens, not even in the halls of the United States Congress.

Mr. PALLONE. So that is why this discrimination issue affects us all and why we have to deal with it.

Dr. COLLINS. It absolutely does. We are all at risk unless we solve this problem.

Mr. PALLONE. All right, then let me ask Ms. McAndrew; well, this is what I wanted to ask. I know you deal with the privacy issue. The Bush administration has issued two Statements of Administration Policy in response to the Senate passing this bill. In both of those cases, the administration said that they favor an Act of legislation to prohibit the improper use of genetic information in health insurance and employment, and as recently as January 17, President Bush said, and I quote, "I really want to make it clear to the Congress that I hope they pass legislation that makes genetic discrimination illegal."

In other words, if a person is willing to share his or her genetic information, it is important that that information not be exploited in improper ways and Congress can pass good legislation to prevent that from happening. What I want to ask, with regard to GINA, am I correct in assuming that you or your office agree with President Bush and support the legislation before us today? I know you mentioned a little bit about it, but if you could just answer that.

Ms. MCANDREW. Yes, we are in support of the nondiscrimination provisions of this bill and they really are beyond the scope of the Privacy Rule, to effect, and we are in support of this legislation to address those problems.

Mr. PALLONE. Thank you. Thank you. I yield to the gentleman from Georgia, Mr. Deal.

Mr. DEAL. Thank you, Mr. Chairman. I am going to ask a series of questions, Mr. Kuczynski. I am going to start with you. And I think they lend themselves to rather short answers and I would like to get through as many of these as I possibly can.

Under title II of H.R. 493, can the practices, actions or communications of in-house healthcare be a basis for violations under 202(a), 202(b) and 206(b) of the Act? To clarify, I mean providers employed by an employer covered by the bill to provide healthcare services as a benefit for employees. Examples, of course, being in-house clinics, hospitals or universities that provide health services to employees as a benefit of employment.

Mr. KUCZYNSKI. Yes, I think that if the employers providing health services as a benefit of employment, that benefit of employment would be subject to nondiscrimination requirements of title II, as it would be with respect to all of the other—it is the same principle as would apply under any of the civil rights laws that we enforce.

Mr. DEAL. Would the same rule apply if the employer contracted with a doctor to provide healthcare services to an employee? In other words, could the practices, actions or communications of such a provider be the basis of a violation under sections of the Act?

Mr. KUCZYNSKI. Again, if the employer is contracting with a third party to provide health services on its behalf, the employer has to ensure that that provider is conducting itself and providing those services in a manner that does not discriminate under GINA. Again, the same is true under the Americans with Disabilities Act, where we have said that an employer can't do, through a third party, what it could not do directly, so the employer would be liable.

Mr. DEAL. That would be yes, they would be considered violations of 202(a), 202(b) and 206(b) of the Act?

Mr. KUCZYNSKI. Yes, the employer could be responsible for those.

Mr. DEAL. OK. I understand that the uniformed military service is exempt from the bill. Would the actions or communications of a healthcare provider employed or contracted to by NASA, the FBI, the Border Patrol or State governments be covered under the Act?

Mr. KUCZYNSKI. They would be as they are under the other civil rights laws.

Mr. DEAL. If an employer offered to provide a service to provide for and maintain electronic personal health records, would that activity be subject to sections 202(b) and 206(b) of GINA?

Mr. KUCZYNSKI. If that involves the provision of health services under GINA, then the individual would have to give a prior knowing, written, voluntary consent to the provision of their services, but yes, the employer would have to make sure that those services were provided in a way, including maintaining the confidentiality of that information that was in compliance with GINA.

Mr. DEAL. I take your answer, then, to be yes?

Mr. KUCZYNSKI. Yes.

Mr. DEAL. Would the same rule apply if the employer contracted with a private company to maintain personal health records in a storage service for their employees? If the employer provided family medical history, for example, to be placed in such personal health records stored at the private company, is that fact alone a disclosure and violation of section 206(b) even if the company agrees to keep such material confidential?

Mr. KUCZYNSKI. I don't think I understood the last part of the question. If the employer is contracting with a third party to maintain the electronic records and there is a disclosure that would violate GINA?

Mr. DEAL. Yes. Is the fact that they are storing it, even though they agree to make it confidential?

Mr. KUCZYNSKI. I think that the fact that they are storing it, I don't think would be. I think the violation would be if the information was disclosed. Again, this is assuming that the individual has given prior knowing, written and voluntary consent to the provision of the health services. They have done that. They can be stored, if they are disclosed in violation of section 206, that would be a violation.

Mr. DEAL. Would the fact that they are being stored by an outside contractor make any difference?

Mr. KUCZYNSKI. No, but the responsibility for and the violation, the liability would be the employer's liability. The Act, as I understand it, doesn't regulate so much the practices of the provider, be it a healthcare provider or an entity that is storing the records, it

is regulating the conduct of the employer and it is saying to the employer you are responsible for making sure that entities with whom you contract are carrying out their functions in a way that is consistent with the requirements of this Federal law.

Mr. DEAL. So if they contract with a private company, then any practices, actions or communications of that private company could be the basis for a violation under section 202(a), 202(b) and 206(b) of the Act, is that right?

Mr. KUCZYNSKI. Well, communications that violate 206, I mean, to the extent that there are communications that are conducted in the normal course of business, sharing information, be it the provider of storage, if an entity is storing records or if an entity is providing health services, I think that they would be permitted to exchange information to the extent necessary to provide those health services or to the extent necessary to store the information.

Mr. DEAL. But that would only be to the extent allowed under 206(b), is that right?

Mr. KUCZYNSKI. Well, I mean, I think there is a question as to whether this law really is intended to disrupt the manner in which providers of health services carry on their business. I don't think, for example, that it would be a violation if, in order to provide services to an individual who has agreed to have them provided, that information was shared, let us say, from a doctor to a lab that needed to have that information in order to carry out the health services to which the employee had already consented. I don't think that GINA is inconsistent with that type of sharing of information.

Mr. DEAL. Under title II, assuming there was not a section 209(2)(b), could the practices, actions or communications of a health plan, administered or sponsored by an employer as an employee benefit, be the basis of violations under title II?

Mr. KUCZYNSKI. When employers contract with providers to offer health insurance, for example, on behalf of the employer, the employer is again liable if that benefit is being provided in a discriminatory way. The same would be true under title VII. For example, if higher rates were charged to women than to men, it would be sex discrimination or fewer benefits were offered to African Americans than to whites.

Mr. DEAL. So I take that to be a yes, then?

Mr. KUCZYNSKI. Yes.

Mr. DEAL. I would like your interpretation of section 202(b)(5)(b). Assume that genetic monitoring is not required by Federal or State law and the business nonetheless feels that safety requires such monitoring. If the employee says that he does not want to be subject to such monitoring, does the employer still have the right to reassign him away from the position that the employer feels needs monitoring or must the employer allow the employee to continue without the monitoring?

Mr. KUCZYNSKI. I think the monitoring under the section that you cited has to be consented to voluntarily and if a condition of submitting to that monitoring, if you don't submit to the monitoring the result is going to be that your employment is going to be adversely affected, then I think it would render the monitoring not voluntary and would render it a violation of the section concerning

voluntary monitoring. Again, the same would be true in an analogous situation with the wellness program under the ADA.

The ADA says employers can offer voluntary wellness programs, but we have said that in order to be truly voluntary, the program can neither require participation nor penalize individuals for nonparticipation. I think in this case, if the person's employment status was adversely affected as a result of non-consent to the monitoring, then it would be a violation of GINA.

Mr. DEAL. Dr. Collins, a reading of this statute, reference is made to detecting a genotype. Does that reference to detecting a genotype cover pharmacogenetic tests?

Dr. COLLINS. Pharmacogenetic tests or sometimes called pharmacogenomic tests is one that analyzes whether an individual has a variation that might predict whether a particular drug is going to be beneficial, whether it would fail to help them or whether it might even cause a toxic side effect, we are learning how to do that increasingly for an increasingly long list of drugs. This is a test of a genotype.

Mr. DEAL. So it would qualify?

Dr. COLLINS. It would be covered under the language that is present in GINA.

Mr. DEAL. Does the definition also cover forensic DNA identification tests, tissue typing for organ donation and paternity tests?

Dr. COLLINS. To the extent that those tests are conducted in a way that detects genotypes, mutations or chromosomal changes, they would qualify as genetic tests and to the extent that they were contemplated as being used to make decisions about health insurance coverage or employment, then they would be protected under the provisions of this bill.

Mr. DEAL. One very quick last one. My understanding is that if someone is determined to have O or AB blood types, it also detects that that person is an O or AB genotype. Do you agree?

Dr. COLLINS. I do. That is a circumstance where the analysis of the AB or O protein is actually a direct correlate with the genotype of that individual, so it is making a very precise prediction about genotypes, so in that instance, yes, you have a circumstance where a protein directly detects the genotype and therefore it would qualify and be protected under the provisions of this bill. I might add that ABO blood type can be a risk factor for disease. That is not widely known. The very first association ever reported between a genetic variation and a disease was ABO blood type and Hodgkin's disease.

Mr. DEAL. Thank you, Mr. Chairman.

Mr. PALLONE. Thank you. I recognize the gentlewoman from California, Ms. Eshoo.

Ms. ESHOO. Thank you, Mr. Chairman. I am sorry I have had to try and divvy up my time between here, obviously the Floor and some other things. Again, thank you to everyone that is testifying today. We need you, we are grateful to you, and what you tell in this part of the record is a very important part of this effort.

Dr. Collins, your testimony has cited several studies demonstrating that people are afraid of discrimination on the basis of their genetic information. In many ways, you are one of the parents of this effort, because you pointed this out a long time ago. Can you fill

that out and instruct the committee about the frequency of it, the number of people refusing the opportunity to take a genetic test?

Has this grown since the mapping took place? And also, how the fear manifests itself relative to doctors that provide the appropriate preventive care? Because this is another area, I think, where it is affected and at any rate, can you fill that debate out and give us more about it? It will broaden and deepen our understanding of it.

Dr. COLLINS. I would be happy to.

Ms. ESHOO. Thank you.

Dr. COLLINS. And I should say that in the second panel, because I have looked at the statements, Dr. Hudson will present you with new statistics just collected in the last week or so about this public concern based on a statistically valid survey indicating that, in fact, something like 80 percent of the members of the public are deeply concerned about this issue of genetic information being used against them, particularly in health insurance, but also in employment. And that is a consistent response that we have been seeing now over the course of some 10 years since those surveys have been taken. I see no evidence that there is any diminution in that concern and that is despite the fact that many States have passed genetic nondiscrimination legislation.

Ms. ESHOO. How many States, Dr. Collins?

Dr. COLLINS. More than 40 States have either a health insurance or an employment provision or both, but again, I think people who have looked at that realize that there are loopholes and you never quite know what State it might end up in a few more years. And if you really want complete protection in this country, it ought to be at the Federal level. So the concerns, as I mentioned, are largely about the anxiety about health insurance in the workplace.

When you look at what this means on the ground, in terms of how people are facing the possibility, not hypothetically, but in their own lives about having such a genetic test, the best data we have comes from studies we do at NIH. We invite people who have had a strong family history of a particular condition to participate in a research study that will involve some genetic testing. We have done this particularly for breast cancer and we have done this for colon cancer in families like the one I mentioned in my opening statement.

And it is actually quite consistent and quite disturbing that roughly one-third in each of the studies that we have done of people who otherwise wish to go through the testing, wish to have the data, were convinced it would be useful to them to know if they were at high risk ultimately decide not to take the test because of this concern that the information might leak out. And this is despite our assuring them that we try to keep careful records, that we have certificates of confidentiality and so on. This goes deep enough that that is not reassuring.

The family I told you about is still walking around out there, with many individuals, at high risk for colon cancer, untested because of this concern and at serious risk of having a very bad outcome and here is a condition that we know how to prevent, knowing you are at risk, getting into a screening program with colonoscopy is life saving. In terms of what it means with health professionals——

Ms. ESHOO. Can I just inject something?

Dr. COLLINS. Yes.

Ms. ESHOO. I think my colleagues, that what Dr. Collins has just referred to, that is an extraordinary amount of fear, to not act on the diseases that he just mentioned. I mean, imagine; people knowing that they have it, have something very serious and not exercising to do something about it because of this fear. So I just kind of wanted to highlight that.

Dr. COLLINS. Another example of how this plays out in a very disturbing way in medical care is individuals who decide they do want to go through with the test but are fearful about this may do so by using a false name. To get the results back, they may have to tell their health provider, ask their health provider not to put it into the record because then it might find its way into an insurer's database and so you have a patient asking their health provider to not tell the truth about information that may be critical for their future medical care.

What is wrong with our system if it encourages that kind of very distressing behavior which, need I say, is bad for medical care, as in the example I briefly mentioned in the opening statement of a physician who ended up with metastatic ovarian cancer which might have been detected earlier, except her provider and the radiologist who was doing the study of a particular pelvic ultrasound didn't know she was at high risk because she had been tested under a false name. What a strange and sad situation.

Ms. ESHOO. Thank you very, very much.

Mr. PALLONE. Thank you. Dr. Burgess.

Mr. BURGESS. Thank you, Mr. Chairman. Dr. Collins, I am going to assume you have genetic counselors talking to these patients?

Dr. COLLINS. Yes. And genetic counselors are absolutely critical to convey this very complex information.

Mr. BURGESS. I don't know. I am just internalizing this conflict for myself. I think my fear of colon cancer would far outweigh my fear of discrimination at any level, but that is——

Dr. COLLINS. And I agree with you and I am startled by those statistics, as well.

Mr. BURGESS. Would your understanding of the bill that we have before us, the bill that we are discussing, would it cover the different mutations, the chromosomal changes that would be present in tumors, if you got, say, receptors on the breast cancer, this type of study would be covered under this Act, is that correct?

Dr. COLLINS. So again, the way the language is written, as far as the definition of a genetic test, this, if it is related to a manifested disease, which in this case would be a breast cancer, this would not cover a measure on that particular thing that was of proteins or metabolites, but it would if it was a DNA test. So if you did a per 2 analysis that was based on DNA or RNA, that would be protected information according to the language of the bill.

Mr. BURGESS. And just to take one step back to Chairman Deal's question about the blood types, would the Rh factor also be protected information?

Dr. COLLINS. It would be protected information in the sense that it detects, even though it is done as an antibody test, it detects, specifically, the presence of a particular genotype.

Mr. BURGESS. I realize it is a little bit of circular logic, but would someone be in violation of the law by putting a charge of RhoGAM on a patient's super bill, thereby the inference is they must have had an RH negative blood test, but thus we have disclosed genetic information?

Dr. COLLINS. I think one should pay close attention to this rule of construction which says nothing in this bill should be construed to limit the authority of a healthcare professional who is providing healthcare services with respect to an individual to request if such an individual or a family member of such individual undergo a genetic test, which would mean it would be entirely appropriate to know whether a woman is, in fact, RH negative as part of their routine OB and GYN care, which I know you are very much in charge of, as a physician.

Mr. BURGESS. Correct, but is the act of charging for the RhoGAM, is that an unauthorized disclosure of that patient's RH negative status?

Dr. COLLINS. Disclosure to whom? I am not sure I am following.

Mr. BURGESS. To the insurance company, to Sigma, Aetna, Medicaid, whoever is the third party payer.

Dr. COLLINS. Well, surely if you have any kind of genetic testing that you are expecting the third party payer to cover, which we certainly expect third parties should cover, otherwise the advantages of all these discoveries aren't going to happen, that cannot very well be a violation of this bill. The insurance company cannot request or require, but they can certainly see the information in order to arrange for reimbursement.

Mr. BURGESS. So the insurance company would not be able to say we need verification that patient was RH negative.

Dr. COLLINS. Yes, they can ask for proof of that, but they could not demand or require or request it if it had not already been medically indicated. Again, I hope, in this regard that I am not treading into territory that I, as a non-legal expert and not precisely——

Mr. BURGESS. Don't worry about it. I do it every day.

Dr. COLLINS. All right, I will do my best.

Mr. BURGESS. It never stops anyone here. Let me just be sure that I do, before we leave this side, let me just be sure I understand. You have the bill in front of you?

Dr. COLLINS. I do.

Mr. BURGESS. Page 15, down about at the bottom quarter of the page where it starts out, "In general," we get into the definition of a genetic test and the language, "There is the occurrence of a disease or disorder in a family member of the individual," not to be limited to heritable genetic disease. So would that include infectious or contagious diseases within family members that would be the subject of this legislation, as well?

Dr. COLLINS. I am not sure I have the same version, but I think I see where you are referring to.

Mr. BURGESS. Bottom of 15, top of 16.

Dr. COLLINS. In my version it is more like 9, but anyway, I think, yes, I am looking at the version which is offered by Mr. George Miller of California, which is the substitute to H.R. 493 that came out of the previous committee. So the intention, certainly, of this bill is to include family history as part of genetic information. Let me

explain why that needs to be, because there has certainly been a good deal of discussion about that and some of the State provisions do not include family history.

At the present time, most genetic tests that are offered to people in terms of giving them a risk of future illness prediction are triggered by the discovery of a family history. The family I told you about with colon cancer wouldn't have been offered a test, except that there were a number of affected individuals.

If family history is not included in the definition of genetic information, then you can imagine a circumstance where a test is positive, but the family history is used as the reason to discriminate and that would rather destroy the purpose of the whole provision in the first place, so I think most of us who have looked at this over now 12 years of talking about these definitions would agree that family history absolutely has to be part of the definition. But then, you are asking family history——

Mr. BURGESS. But what about a contagious or an infectious disease?

Dr. COLLINS. So again, infectious diseases do have hereditary contributions in terms of potential risk. Interesting anecdote. In those individuals in Asia, for instance, died of avian flu, there are some examples where in one household more than one individual has dies. You have yet to see an example where both spouses have died, but there are many instances of a child or siblings. That tells you there is some genetic contribution to susceptibility to flu. We know that is true of many other infectious diseases.

So I don't think it is possible to absolutely draw a bright line between what is an infectious disease with no genetic component and what is a genetic component for another type of disease, so I think the language that is in here basically covers the circumstances. I can't imagine, although, if you were interested looking at a circumstance where an infectious disease was placing an individual at risk because it was occurring around them, but you would limit that examination to family members.

Mr. BURGESS. Just one last question on this subject. Would that meant that data would have to be segregated from the balance of the patient's clinical data?

Dr. COLLINS. No, the only segregation, as I understand it in this bill, of separate information relates to employer records.

Mr. BURGESS. OK. Ms. McAndrew, let me ask you a couple of questions, if I could. Currently, health plans in the country are subject to the Privacy Rules under HIPAA, is that correct?

Ms. MCANDREW. That is correct.

Mr. BURGESS. And the HIPAA Privacy Rule recognizes that there are a number of important uses and disclosures of information by health plans that are necessary for payment purposes and to conduct normal business operations. Fair statement?

Ms. MCANDREW. Yes.

Mr. BURGESS. Does title I of H.R. 493 alter in any way the ability of the health plans to use and disclose information, including genetic information for normal payment and normal business operations purposes?

Ms. MCANDREW. We would need to take a close look. It would not appear that, with regard to claims processing, that there is any af-

fect on title I, from title I on that activity. It does, however, prohibit the use of genetic information for other types of activities for which the Privacy Rule currently allows a health plan to engage in with regard to other types of protected health information, such as premium rating, enrollment and determination of eligibility for benefits. Those would become discriminatory uses under title I and prohibit the use of genetic information with regard to those particular purposes.

Mr. BURGESS. So it would prohibit the disclosure of that information?

Ms. MCANDREW. It would prohibit the use of, by the health plan, of genetic information for those purposes.

Mr. BURGESS. OK, just going back to my RhoGAM example, is that a concern here?

Ms. MCANDREW. To the extent that information was submitted to the health plan for a payment purpose, it would not appear to be an impermissible use under this bill, but if it were——

Mr. PALLONE. Doctor, we have got to move on. We are over almost——

Mr. BURGESS. Mr. Chairman, let me, if possible, since this is so important that we get this legislation, because I told Dr. Collins he is moving really fast with his science, and I am glad he is, and we move really slow up here and anything we——

Mr. PALLONE. Twelve years, to be specific.

Mr. BURGESS. Anything we do is going to be that way for the rest of our natural lifetimes, so would it be permissible to submit questions in writing?

Mr. PALLONE. Oh, absolutely.

Mr. BURGESS. OK.

Mr. PALLONE. Any Member can submit questions.

Mr. BURGESS. Thank you, Mr. Chairman.

Mr. PALLONE. Thank you. Mr. Green.

Mr. GREEN. Thank you, Mr. Chairman. I want to follow up my colleague from Texas' question, Ms. McAndrew, although, Dr. Collins, I have questions for you, too, but following that line of questioning, it would be impermissible use. My concern is if the information is available, it is very difficult to find out why they denied someone coverage and maybe some States, because my experience in dealing with health insurance in the State of Texas, for example, if you are denied coverage for an individual policy, now, group policies have protections, but for individual, but if it is even provided, there might be some other reason they would deny coverage. Is there a concern on that?

Ms. MCANDREW. As I understand the way this is structured, I don't think it would be any different than the current HIPAA title I prohibitions with regard to the use of genetic information for some health plans and to prohibit discrimination and discriminatory policies with regard to that. That does not bar the health plan from obtaining this information and much of this information, as was indicated earlier, may need to come to the health plan in order for them to adequately, to pay for the services that these individuals need in getting these genetic tests. I think the proper limitation is on the misuse of that information for this nondiscriminatory practice.

Mr. GREEN. But again, the misuse of it, how do you prove that in a court of law or if you even get to the court? Because in so many cases if a claim is denied and they happen to know that information that your genetic background is diabetes, for example, and the claim is denied, maybe, because that was a preexisting condition, but that is my concern and I share Dr. Burgess' concern about that.

I am concerned about disclosing it, period, because I think families who have the fear of the disclosure would say well, it is hard for me to get insurance, anyway, and if that information is available, no matter what they use; they may use something else. We are not underwriting in your zip code or you are blocked or something like that, that is not discriminatory.

Mr. Chairman, I want to make sure that our final draft, whatever comes out, that we look at that issue—that disclosure is a concern not just that they are prohibited from using that information. I think it ought to be prohibited use, but I also think the disclosure is something that families will still be afraid of disclosing that to health plans.

Dr. Collins, some people express concern that the legislation singles out genetic information as being fundamentally different than other types of health information. This is called genetic exceptionalism. What is the justification for treating genetic information differently than some other health condition?

Dr. COLLINS. That is a very appropriate question because obviously, we don't, by doing something that is really needed here. We try to provide protection for something the public is quite concerned about, mainly genetic discrimination. We don't want to somehow set genetic information into this area that sounds even scarier than any other type of medical information and yet, it is different in certain ways.

I have this mantra of the six P's that make genetic information separate from other types of medical information. No single one of these would qualify, but you put all six together and you can see there is something different here, so let me try my six P's out on you. What is it about genetic information? It is predictive. It says something about what might happen in the future while you are still well. It is prejudicial. It is the kind of information that can be used against you. That is why we are all here this afternoon. It is permanent. Your DNA is going to be your DNA while you are here. It is not like your blood cholesterol or your serum sodium that might change next week. It is what it is.

It is, this is a littlie bit of a stretch, pedigree relevant. That is to say it affects not only you, but your relatives and what you find out about yourself may shed light on your kids or our parents or your siblings. It is, in the view of most people, personal. There is something about DNA, our own instruction book, that is a little different than saying well, my white blood count today is 5600.

And finally, and attached to that personal is most people think it should be private. It is not the sort of thing you want on the Internet or the front page of the Post. So you take those six things together and you can see that genetics fits into all of those and other types of medical information doesn't quite create that same

sense of specialness and hence, the appropriateness, I think, of trying to provide special protection.

Mr. GREEN. Thank you. Mr. Chairman, I know I have run out of time, but I have just one question I would like to throw out to take a yes or no to Mr. Kuczynski of the EEOC. I know the previous chairman of the EEOC expressed support for this legislation. Is the current chairman, Naomi Earp, is she also in support of this legislation from the EEOC?

Mr. KUCZYNSKI. I believe that the chair is in support of legislation that would prohibit the type of genetic discrimination that I have described in my opening statement, yes.

Mr. GREEN. OK. Thank you, Mr. Chairman.

Mr. PALLONE. Thank you. Mrs. Myrick.

Mrs. MYRICK. Thank you, Mr. Chairman. And my question is for Dr. Collins and first of all, thank you for the fine work you have done. It really is very exciting and we have all come a long way because of it. But I wanted to ask about clinical trials because I understand one of the goals of the bill is to try and remove unnecessary barriers to participation in clinical trials and I know a lot of times that scientists have told me they have trouble getting people to participate in clinical trials; it is difficult.

As you mentioned, people are scared that some of their genetic information about disease will be made known to their insurer or their employer and so I am curious why the bill doesn't explicitly mention that genetic disease related clinical trials are covered under the nondiscrimination umbrella and I wanted to ask you if you see this as a potential problem?

Dr. COLLINS. So certainly, we would not want anyone who is contemplating participating in a clinical trial to have this fear of discrimination to be a deterrent. We depend on people's generosity with their time, with their very lives, to take part in these trials so that we can advance the course of medicine. I think when it comes to this specific area of genetics, however, the provisions of this bill largely make that a non-issue in specific ways, because the bill does, after all, comment upon whether, in fact, one may allow the use of genetic services, the request or receipt of genetic services, to be used to discriminate and the bill specifically says no.

H.R. 493 says that is not permitted. Genetic services are defined in the bill as (A) a genetic test; (B) genetic counseling; and (C), genetic education. Those three things are all part of the kinds of clinical trials that we currently conduct that involve genetics, so anyone who is part of such a trial has essentially, then, received genetic services and those may not be used, according to the language in this bill, as a means of discrimination. So I grant you, the larger question of clinical trial participation may need attention, but in the specific instance of genetics, the language that is in this bill appears adequate to cover that situation.

Mrs. MYRICK. So you feel it is covered, without question, in the bill, that people are protected?

Dr. COLLINS. The genetic component of clinical trials, yes.

Mrs. MYRICK. OK. Thank you very much. Ms. McAndrew.

Ms. MCANDREW. Yes.

Mrs. MYRICK. A couple questions here. For entities that are covered by HIPAA Privacy Rule, how long is the list of permitted disclosures?

Ms. MCANDREW. We have, first, identified those disclosures that are core to the business of providing treatment and getting that treatment paid for and as I mentioned, the first carve-out from the need for an individual written authorization in order to use information or disclose it to others is for treatment, payment and healthcare operation purposes. And that permits the ready use of this information for its intended purpose, to treat the individual, get that treatment paid for. Outside of that, we do have a number of other public purpose disclosures.

Mrs. MYRICK. Like what? I mean, what would you——

Ms. MCANDREW. We have, for instance, we would permit a disclosure as required by other law. We would permit a disclosure of information for public health purposes. There is an exclusion for health oversight activities. There is an exclusion for judicial and administrative proceedings. There is an exclusion for research. Now, all of these come with their own separate list of conditions and other protections before an entity is permitted to release identifiable information for any of these purposes. But the basic balance is that the need for the information for these important public purposes overrides to one degree or another the necessity to get the individual's prior written permission before that disclosure is made.

Mrs. MYRICK. Well, if we enacted a broad prohibition on the use and disclosure of information by employers, in your experience with implementing HIPAA rules, do you foresee any issues that would arise from the obstruction or the routine flow of information? Is there anything that would be a potential problem?

Ms. MCANDREW. Well, I think the balances would need to be worked out. I don't have any particular expertise with regard to what the normal practices would be in an employment setting. The HIPAA balances were all structured in the healthcare delivery and healthcare payments study and were really restricted, in particular, to that need for the information and the collection of health information in the first place. And so looking at any other sector, whether it is the business sector, and I think employment may be particularly complicated only because of such a wide range of businesses that would, that are employers whose need and legitimate need for the information would need to be weighed and balanced.

Mrs. MYRICK. I appreciate it. Thank you, Mr. Chairman.

Mr. PALLONE. Thank you. Mrs. Capps.

Mrs. CAPPS. Thank you, Mr. Chairman, and thank you to each of our witnesses for their testimony. Many of us are here in this hearing because of our concern that the public's fear of getting tested for genetic conditions may interfere with taking full advantage of what genetic testing has to offer in terms of prevention, early detection, early treatment. Perhaps, however, we assume that the public understands exactly what this is and what it might involve.

To start us off, Dr. Collins, you are a physician as well as a geneticist. You gave some compelling illustrations of colon cancer and understanding the gene in the role that it could play. Perhaps, for the record, you would start us off with just briefly mentioning a

couple of other situations that might indicate the purpose for this hearing.

Dr. COLLINS. I appreciate the opportunity to do so. So certainly, the colon cancer example is one where we already know that interventions can be life saving. That list, though, is growing. Certainly, with breast and ovarian cancer, the BRCA1 and BRCA2 genes, which, if misspelled, can confer a rather high risk of both of those cancers, are now at the point where there is clear evidence that knowing your status can, in fact, improve your likelihood of long-term survival and that has now been implemented in the hands of many healthcare providers.

And yet, I just read a report that came from this past weekend's Society of Gynecological Oncology, that only a tiny fraction of women who are at risk, based on their family history, are actually taking advantage of that test, a really frighteningly small number are doing so. That particular study did not investigate why, but I know from everything we have been able to document at NIH, that discrimination and the fear of it has certainly been a major factor in that.

Other types of tests, certainly we are learning more and more about this business of how to identify risks of a bad drug reaction, which could be, in fact, very important in preventing some of those outcomes. There is a particular drug that is used to treat children with leukemia, six-mercaptopurine. If you are one of those one in 300 kids that has a particular misspelling of the gene that coats for the enzyme that metabolizes that, then this drug, instead of helping cure your leukemia, could actually be fatal.

We now know how to test for that and so it is possible to do so before administering the drug. In fact, produces even better than that. Those kids that have that particular situation can still receive the drug, but at one-tenth the dose and they still have a very high likelihood of being cured of their disease. You can imagine that that kind of test might be seen by some as a risk factor, might therefore end up being utilized in ways that we all would find inequitable and unjust.

And there are other examples in terms of drug testing. The drug that is given for blood clots, something that we have been reading about in terms of a high number of the administration this week, warfarin, which is used in millions of people, is also one of those that has a lot of side effects. We are on the brink of figuring how to predict those and being able to offer a test prior to administering the drug to reduce that risk. Other tests for diabetes are coming along fairly quickly. A lot of things happening there in terms of understanding hereditary risks.

Mrs. CAPPS. Thank you. And we could go on and on, I know.

Dr. COLLINS. I probably would if you didn't stop me.

Mrs. CAPPS. In the next 1 minute and 45 seconds, I want to get to people not getting tested. This also has a effect on their own healthcare. But mention, if you would, some ways that it would also inhibit biomedical research and clinical trials, because it means fewer people will volunteer for clinical research and individuals there will not be tested for preventable disease. And if you have a second at the end, if you would, talk about the need to include family members, as well as the individual patient.

Dr. COLLINS. Great questions. Already at NIH, this is a serious issue. We are at this point in medical history where we have the opportunity to discover what really are the genetic and environmental causes of illness. In order to do that, we need to have individuals willing to volunteer to have their environment studied and their genetics studied. And if fully a third of the people who otherwise want to participate walk away, then we have lost out. We have lost out in a way that is bad for them and bad for us.

And especially, as you say, in circumstances where you are trying to look especially at heredity, you are very interested in enrolling families so that you can see how a particular genetic variation has passed through the family and conveyed a risk or sometimes a protection against disease and if even some members of the family are afraid of discrimination, then the whole family may end up not participating and we lose out. We lost out, as a country, on the opportunity to learn more. We could take care of that. Thomas Jefferson's words on the Jefferson Memorial over there, "Our laws and institutions should keep pace with the progress of the human mind." Here is the opportunity to make that happen.

Mrs. CAPPS. What a wonderful statement. Thank you very much.

Dr. COLLINS. His words.

Mr. PALLONE. What a great way to conclude this panel. Thank you, Doctor. Thanks to all of you. I think we have finished with the questions, but this really was a fascinating exercise to listen to all of you and obviously made the case very well for why we need to move legislation, so thank you again. I appreciate it.

I would ask the next panel to come forward.

There are seven of you, so we are going to ask you to try to keep your comments to the 5 minutes,if you see the red light, please try to summarize and end because otherwise, we will be here all night. Let me welcome you all and introduce all of you to the committee.

We have Ms. Sharon Terry, who is the chair of the Coalition for Genetic Fairness and president and CEO of the Genetic Alliance. We have Dr. William Corwin, who is medical director, Clinical Policy for Harvard Pilgrim Health Care. And then we have Mr. Burton Fishman, who is with Fortney and Scott. And then we have Ms. Pollitz, who is a research professor at Georgetown University Health Policy Institute; Mr. Frank Swain, senior vice president, B&D Consulting and former chief counsel, Advocacy at the United States Small Business Administration.

Ms. Janet Trautwein, executive vice president and CEO of National Association of Health Underwriters. And last, Dr. Kathy Hudson, who is director of the Genetics and Public Policy Center and associate professor of the Berman Institute of Bioethics of the Institute of Genetic Medicine, Department of Pediatrics at Johns Hopkins University.

Thank you all for being here and we will start with Ms. Terry.

STATEMENT OF SHARON TERRY, CHAIR, COALITION FOR GENETIC FAIRNESS, AND PRESIDENT, CHIEF EXECUTIVE OFFICER, GENETIC ALLIANCE, WASHINGTON, DC

Ms. TERRY. Chairman Pallone, Representative Deal, and members of the subcommittee, thank you for bringing us to this moment and for the opportunity to testify here. Representatives Eshoo,

Slaughter, Biggert and Walden demonstrate robust vision and courage to introduce again the legislation that will make it possible for Americans to benefit from new technologies and tests. My name is Sharon Terry. In some way, I am the least qualified person to appear before you. I don't have the professional qualifications of those who testified today. And in other ways, I am the most qualified. I represent millions of Americans affected by genetic conditions.

I am president and CEO of Genetic Alliance, a coalition of more than 600 disease support groups and I am the chair of the Coalition for Genetic Fairness. Mine is not a chosen profession. It is a vocation thrust upon me when my children were diagnosed with a genetic condition that will rob them of their vision in the prime of their life. Quite poignantly, the Genetic Information Nondiscrimination Act of 2007 will not protect my children nor the millions I officially represent. They all have manifest disease and this bill appropriately does not protect them. This is a critical point often obscured in many of the arguments against the legislation.

The bill is not about those who already have signs or symptoms of disease, but rather about those who carry a genetic mutation which increases their chances to develop a disease. Though my family will not benefit, I have worked on this legislation for 12 years, since Congresswoman Slaughter first introduced it. With others present here, I founded the Coalition for Genetic Fairness to support this legislation and we have had a long and uphill battle. We are several hundred organizations strong and include many sectors of our society, including disease support groups, health professional organizations, women's leadership groups, labor groups and most significantly, companies like Affymetrix, IBM and 20th Century Fox. We thank them and those of you, who year after year, have supported this legislation. We have compromised and conceded a great deal during these years and we believe the bill before you is fair and well-balanced.

My passion for more than a decade has been fueled by the faces and the voices of the hundreds of individuals who have contacted us, fearing for their children, their lives, their jobs, their insurance; men, women and children, families from communities all across this country, who have told us their stories and in some cases, pleaded for us to help them.

In 2003, Heidi Williams of Kentucky called me when her children were denied insurance by Humana, Incorporated. Heidi has alpha–1 antitrypsin deficiency, an autosomal recessive genetic disease. Humana rejected the children's application stating that the children were carriers and so they could not cover them. With our help, Heidi explained in an appeal that carriers are not affected, but Humana again denied the insurance. I called a reporter from a prominent national newspaper, they called Humana and that night Heidi's children were covered retroactively.

Some families are not lucky enough to have a connection with our coalition or a reporter to help them. This year, Heidi's daughter wrote a letter to her Congressman.

Dear Congressman Ron Lewis, My name is Jayme Williams and I am in the fifth grade and live in Cecilia, Kentucky. My brother and I are carriers of alpha–1 antitrypsin deficiency, a defective gene in our DNA that can be passed on to our

future children. While my brother and I have only one defective gene, my mother was given two and her lungs are very sick. My brother and I were denied health insurance because we carry these mutations. My mom tells our story because other people are too afraid to tell theirs. Discrimination makes people very afraid. When people are discriminated against, they are sometimes told they will lose something they need if they speak out against the people causing the discrimination. My mom says that everyone is created equal and deserves to be fairly treated. Please help my mom.

Let resonate these heart-felt words from a young woman who cannot imagine that carrying a mutation in the gene makes her uninsurable. I assured her that we will continue to work hard for her.

I am also reminded of Becky Fisher, who shares a mutation for inherited breast cancer with many in her family. Having watched her mother, aunts and cousins die of breast cancer and she, herself, a survivor, she thinks only of her daughter, who is brave enough to be tested and says of her, "One of the not-so-good things of having a documented genetic mutation makes her more vulnerable to more than devastating disease. She also faces the burden of never knowing when she will legally be asked to take a genetic test as a condition of employment or lawfully fired from a job because of high costs of medical care or denied health insurance."

We are all Heidi and Becky's children. We all carry mutations for dozens of diseases and we are all vulnerable. Aren't health and disease enough to worry about? We cannot afford to also worry about discrimination based on these mutations, silent mutations with no signs or symptoms. This is simply about preventing misuse of genetic information, that which makes up every one of us, our shared inheritance, and that which makes us unique.

This is also about special interests. Let us put the special interests of health of all Americans above all else. Every one of you and each of your loved ones is at risk for some disease or another. We cannot yet easily reduce that risk, but it is in your hands to reduce the risk of discrimination associated with that information. At the end of the day, we are relying on you to make it possible for individuals to use their genetic information for the health purposes for which it was intended.

Some might say that Dr. Collins and his colleagues have done the hardest work, but we understand that balancing the policy needs of the Nation is difficult. You are pushed and pulled in many directions. Please measure your decisions by what truly matters when voting in committee and the full House floor in the next weeks. Please remember that neither you nor any of us have any choice over our ancestry, our different abilities, our genetic makeup. As a nation, we do have a choice.

Every American is affected by this legislation and beyond the health insurance companies, the trade associations and the employers' needs, all those who carry genetic mutations, they did not ask are asking you to take the necessary measures to alleviate the burden of discrimination that this places on our nation. I have faith and hope that you will choose to relieve their burdens, my burdens, your burdens. I look forward to your good work in the weeks ahead. Thank you.

[The prepared statement of Ms. Terry appears at the conclusion of the hearing.

Mr. PALLONE. Thank you, Ms. Terry. Dr. Corwin.

STATEMENT OF WILLIAM CORWIN, M.D., MEDICAL DIRECTOR, CLINICAL POLICY, HARVARD PILGRIM HEALTH CARE, WELLESLEY, MA

Dr. CORWIN. Mr. Chairman, Mr. Deal, members of the subcommittee, my name is Dr. William Corwin. I am the medical director for Harvard Pilgrim Health Care, which is a not-for-profit health plan that provides insurance plan options to more than a million members in Massachusetts, New Hampshire and Maine. Harvard Pilgrim has been named the No. 1 health plan in America for 3 consecutive years. This is according to a joint ranking by the U.S. News and World Report and the National Committee for Quality Assurance. I appreciate this opportunity to testify on behalf of America's Health Insurance Plans, which is a national association for representing nearly 1300 different insurance plans providing coverage to more than 200 million Americans.

Health insurance plans are working on a daily basis to promote the appropriate use of genetic tests to help clinicians and patients make informed healthcare decisions and improve health outcomes. We agree with the sponsors of H.R. 493 that healthcare consumers should not face discrimination on the basis of their genetic makeup and that genetic information should be protected from unauthorized disclosure. Our policies and programs reflect this belief. We have submitted written testimony that focuses on three broad areas: examples of how health insurance plans are promoting the appropriate use of genetic tests to improve patient care; opportunities for improving H.R. 493; and our support for the strong protections with respect to non discrimination, confidentiality of this genetic material.

In the next few minutes I would like to provide some examples of how health insurance plans are promoting the use of genetic information to help our enrollees receive the highest quality, evidence-based care possible. And I also will briefly comment on H.R. 493.

Through early detection that we have heard about earlier, disease management programs and other quality improvement initiatives, we are working to identify individuals who can benefit from early intervention and evidence-based treatment for these specific illnesses and diseases. Genetic information, including the results of genetic tests, is just one of the more sophisticated sources of data that clinicians and the health insurance plans are using to ensure that our patients receive appropriate preventive care, a coordination of services and early treatment for these medical conditions.

I would like to highlight two specific examples of how genetic tests are being used to improve patient care. In February 2007, the Food and Drug Administration approved a new genetic test called a MammaPrint, which indicates whether a woman is likely, with breast cancer, to relapse earlier than otherwise predicted. This test allows physicians to tailor therapy for individual patients and administer chemotherapy to only those patients who would benefit. At the same time, the test allows physicians to identify patients who would not benefit from chemotherapy and avoid unneeded chemotherapy or risky and costly treatment.

Another test that we heard about earlier, the Cytochrome P450 enzymatic test is genetically coded. The identification of the pres-

ence or absence of this genomic marker enables a physician to evaluate a patient's ability to process many different kinds of medications, adjust doses intelligently, and to avoid potential adverse drug reactions in patients who either metabolize a drug too quickly or do not metabolize that drug at all well. This test also is used to determine how children with certain forms of leukemia will respond to various doses of chemotherapy. Health insurance plans may request that this test be performed before authorizing a course of therapy to ensure that the appropriate care, evidence-based care, is being provided to meet the patient's best individual patient centered needs.

Health insurance plans are also using genetic test results to promote preventive screening, disease management programs and other programs to help improve healthcare for individuals who have tested positive for a genetic disease or who have a family history of a specific disease or condition. For example, individuals who have the gene for the familial form of colorectal cancer, can receive coverage for more frequent preventive screenings. Physicians can receive reminders that these screenings need to be done.

As scientists acquire a greater understanding of the role genes play in disease and develop more targeted therapies and treatments and possibly even cures, preventive screening and disease management programs can be tailored to improve outcomes for our individual members. These therapies will become even more important in the future. We appreciate the interest many subcommittee members have shown in passing additional legislation addressing the use and disclosure of genetic information. As you do so, we urge you to fully evaluate the implications of any additional requirements or prohibitions and to ensure that the new legislation does not unnecessarily restrict the use of information needed to promote appropriate healthcare decision making.

Working with AHIP, our industry association, we have reviewed H.R. 493 and identified several areas where we believe changes are needed to ensure that genetic information is available to health plans so we can continue to assure appropriate coverage decisions.

Mr. PALLONE. Dr. Corwin, I know you still have a lot left, so if you want to summarize a little bit? OK, thanks.

Dr. CORWIN. Targeting the programs to improve quality of patient care. We do not oppose the bill. We agree with its intent. However, once enacted, there will be a variety of interpretations about the bill and how its requirements would apply in various settings. To avoid any confusion, health insurance plans would like to encourage the subcommittee members to assure that statutory language clearly reflects your intent for enacting this legislation. Thank you.

[The prepared statement of Dr. Corwin appears at the conclusion of the hearing.]

Mr. PALLONE. Thank you, Doctor. Mr. Fishman.

STATEMENT OF BURTON FISHMAN, FORTNEY & SCOTT, LLC, WASHINGTON, DC, ON BEHALF OF THE GENETIC INFORMATION NONDISCRIMINATION IN EMPLOYMENT COALITION

Mr. FISHMAN. Chairman Pallone, Ranking Member Deal, distinguished members of the subcommittee, present and absent, thank

you for this opportunity to testify on H.R. 493 and the issue of genetic nondiscrimination in the workplace. I am honored to be here. My name is Burton Fishman. I am of counsel to the Washington, DC law firm of Fortney & Scott, and I appear before you on behalf of the Genetic Information Nondiscrimination in Employment Coalition, the GINE Coalition, mainly of employers.

Let me be clear. The coalition strongly supports genetic nondiscrimination and confidentiality and believes that employment decisions should be based on an individual's qualifications and ability to perform a job and on characteristics that have no bearing on job performance. As a result, the coalition supports the goals of this bill. We commend the help of the subcommittee for the important changes it has made and we hope to continue working with this subcommittee, with all Members of Congress, to make genetic discrimination legislation effective, administratively efficient and practical. I have submitted a lengthy statement and I do not intend repeating it and I will focus my comments on the few issues the coalition regards as significant.

When testimony was given on a prior version of this bill in 2004, it was noted, at the time, over 30 States had passed genetic discrimination laws covering scores of millions of people. At that time, not a single case had been brought under any of those laws, let alone a violation being formed. That is still true today. Mr. Kuczynski should have pointed out that the Burlington Northern case was vigorously and successfully enforced under current existing law. We believed then and now that this bill is a remedy in search of a problem.

In light of that and because of the breadth of its definitions and the unintended intrusions this bill will impose on employees, employers, healthcare providers and health insurers, we ask you first to do no harm. We do not want a law that imposes real burdens and actual costs based on distant, contingent eventualities or the inadvertent and innocent conduct of any employer. We share the concerns of Representative Cubin, that we do not want a law that makes knowledge illicit rather than one focused on illicit conduct. We do not want a bill that regulates the flow of information rather than the misuse of information. And I raise these points because the proposed bill could be improved by greater attention to the implications of its various provisions.

As currently drafted, H.R. 493 creates protections for genetic information that far exceeds those for personal health information under HIPAA. We do not understand why information relating to distant, contingent eventualities requires protections greater than those for existing medical problems. We do not understand why a separate protective program needs to be invented and mastered after employers have labored so long to put HIPAA and privacy programs into place.

Further, the protective program of H.R. 493 does not promote sound public policy. As we have heard, unlike the HIPAA privacy regulations, there is no general exception for disclosures for treatment or disclosures to private and treating physicians, to unfolding police investigations, to identify a victim of a crime or a criminal, to Government officials investigating something other than compli-

ance with this law; you can't even talk to your own litigating counsel under GINA. These exceptions should be incorporated here.

As we have heard again, from Dr. Burgess and others, the definition of genetic information in H.R. 493 dispenses with predictive genetic information or even a relation to an inheritable disease. In its place, we have a definition that is so broad as to, and I quote, "The occurrence of a disease or a disorder in family members of the individual." That's unquote, without any limitation. We share Dr. Burgess' concern that Congress did not intend to have colds, flus, upset stomachs and chicken pox as part of this bill, but as it is written, it does. The definition of genetic information should be limited to predictive genetic information associated with the disease that is not symptomatic at the time of testing.

In the bill, genetic information acquired pursuant to some laws is permitted, whereas that same limitation does not occur for others. For example, you can get information from FMLA certifications or Workers' Comp, but you can't do so from ADA accommodation or helping people get their health insurance, which are far more likely sources of that information. There should be an exception permitting the acquisition of all such information, if collected pursuant to law and retained in confidential files. As our position is the information should not be the issue, the misuse of the information should. I know I have run out of time, so I will end here, thanking you again for this opportunity. I am looking forward to answering your questions.

[The prepared statement of Mr. Fishman appears at the conclusion of the hearing.]

Mr. PALLONE. Thank you, Mr. Fishman. Ms. Pollitz.

STATEMENT OF KAREN POLLITZ, RESEARCH PROFESSOR, GEORGETOWN UNIVERSITY HEALTH POLICY INSTITUTE, WASHINGTON, DC

Ms. POLLITZ. Thank you, Mr. Chairman, Mr. Deal. It is a pleasure to be here today. I am Karen Pollitz and I am an adjunct professor of public policy at Georgetown and I direct research on private health insurance at Georgetown's Health Policy Institute. And I would like to focus my remarks today on the insurance provisions of H.R. 493 of GINA and say a word about what genetic discrimination in health insurance means. If you haven't yet, I would encourage you to read the appendix to my friend, Janet Trautwein's testimony. It is very excellent, it is very thorough and it explains how health insurance works and how it is provided and the whole process of applying for it. And as you read through that, it is pretty lengthy and complete, you won't see the word discrimination in there. You will see words like correct pricing of policies and accurate assessment of risk. And that is because certain practices that GINA would prohibit are legal today and commonly employed, especially in the individual health insurance market.

A key concept in medically underwritten health insurance is really a deal between consumers and the health insurer. The consumer promises to pay a premium and in return, the health insurer promises to protect the consumer against the costs associated with unknown future medical risks. And the medical underwriting process is the process that insurers use to sort out what are the risks that

are already known and that won't be covered under the policy. Medical underwriting is somewhat controversial. Janet and I have had some good fights about it over the years. Some people think it is justified and some people would rather see it go away.

Gradually, the States and the Federal Government have limited medical underwriting practices, much more so in group coverage, much less so in the individual market. But I would make a prediction that it is safe to say its days are numbered. As Dr. Collins has testified, eventually all of us are going to know what our future risks of medical and health problems are going to be, so the concept of unknown future risk is eroding and eventually we are all going to be uninsurable. So then I think we are going to have to figure out something else.

For today, though, GINA would protect discrimination in health insurance based on genetic information and for all the good reasons that you have heard today. I want to tell you a little bit just about how medical underwriting works and how insurers could come to discover this information and of course, people applying for coverage and then tell you about the results quickly of a research project that my colleagues and I just completed.

In the individual market, first, not that many people have individual health insurance. On any given day, most of us get coverage at work and then the next largest source of coverage for people under the age of 65 is the Medicaid Program. So only about 5 percent of the population in any given year has individual health insurance. But we move through it a lot as we are ineligible for those other more common sources of coverage, so over a 3-year period, one in four adults will try to get individual health insurance. They won't all succeed because, for many reasons, but including the fact that it is medically underwritten.

When you apply for medically underwritten health insurance, you have to fill out an application and answer a lot of questions about your health status and depending on how you answer them, the insurer may ask for additional information about you and investigate more carefully your medical history. All applications for individual health insurance has a waiver that you must sign that gives a complete and total access to any and all medical records about you to the health insurer, so if you answer yes to a question have you ever had this or has someone in your family had that, the insurer may then ask for your medical records and begin to dig a little more.

And it is in the course of this digging for additional information that insurers may come across your genetic information because there it is in your medical record. Underwriters tell me that, on average, about 20 percent of applications involve a request for additional information and looking through your medical records. So this is information that is discoverable today by health insurers.

We, as I said, studied medical underwriting practices in the individual market in response to genetic information. It is hard to examine in practice because not that many people have undergone testing, so what we did, in our project, was we asked individual health insurers to medically underwrite some hypothetical applicants and we presented them with four pairs of applicants. And the pairs were pretty much identical, except one in each pair had un-

dergone genetic testing and gotten a positive result, so that we were trying to sort of separate how would you behave with respect to this applicant based on this one thing that is different, their positive genetic test results.

In seven instances, five of the 23 responding companies said that they would take an adverse action based on genetic information. They would deny coverage or they would surcharge premiums or they would exclude coverage permanently, using an exclusion rider for the genetic information and basically call that a preexisting condition. We then went back and asked underwriters what actions they would take based on an applicant's receipt of genetic services. The GINA legislation also protects genetic services, which includes counseling of patients about what steps they might be able to take to reduce the risks that they learn that they have inherited.

Specifically, we asked the insurers again, would they consider an applicant who had a BRCA1 mutation whose doctor had discussed or——

Mr. PALLONE. Ms. Pollitz. I am sorry.

Ms. POLLITZ. I will wrap it up.

Mr. PALLONE. Yes.

Ms. POLLITZ. I just wanted to let you know that 13 underwriters responded to this question. Five said that they would take an adverse action based on this woman having been told about risk reduction options and 10 out of 13 said if her doctor had recommended any, that they would turn her down, charge her more or exclude preexisting conditions.

I would just conclude by saying that Congress and 43 States have already acted to limit discrimination based on genetic information to some extent, but the protections that are out there vary, they are not complete and a comprehensive Federal law that addresses all three of the ways that insurers can discriminate based on genetic information is important to have. Thank you.

[The prepared statement of Ms. Pollitz appears at the conclsuion of the hearing.]

Mr. PALLONE. Thank you very much. Mr. Swain.

STATEMENT OF FRANK SWAIN, SENIOR VICE PRESIDENT, B&D CONSULTING, WASHINGTON, DC

Mr. SWAIN. Thank you very much, Mr. Chairman, Mr. Deal. I appreciate the invitation. This is a piece of legislation that I have been interested in and involved with for only about 2½ years now, so in the history of this project, I am a relative newcomer. I would ask that my statement be received into the record and I would like to summarize a couple of points. I suppose one reason I am here is because I have some experience, professional experience, and it is a matter of personal interest, as well, worrying about the burdens on small business.

I have had a career that has had stops at the NFIB and I was President Reagan's chief advocate at the Small Business Administration, so I am not going to plunge into anything that I really think is going to be a burden for small business. And after listening to Mr. Fishman's comments, I thought well, maybe I am here for the wrong reasons, but I must gently disagree with some of his points. I don't think that this bill is going to be significantly bur-

densome for business and I do think that as the scope of available genetic information accelerates, as it most certainly will and it is doing, that business, in particular, needs the certainty and the predictability of how to handle this information and how to handle it in a way in which they know that as they go about their normal business practices, normal personnel practices, normal insurance practices, that they will not be subject to criticism.

So this is extraordinarily important legislation because business does need the predictability. I would absolutely agree with the points that have been made that there has not been excessive litigation to this point over these issues. Of course, I could turn that logic around and say indeed, although there are 41 or 43 States that have this legislation on the books, it apparently has not been overly burdensome for business in those States, because indeed, there has been not much litigation. But be that as it may, the issue is probably not so much where there is litigation or not.

The issue was amply demonstrated by the prior panel; apprehension and fear about engaging in these tests in the first place, and as individuals have that apprehension and fear, I admit it is irrational in many cases, but medical advances and appropriate treatments will not be accelerated or promoted. We need to have a formula, a set of protections that is predictable for employers and also for individuals so that there is not that factor of apprehension.

I do think that it is important to note that the bill has been adjusted, to some degree, in the prior committee and I think that the proponents of the legislation are not adverse to making specific adjustments that might improve the bill. However, I think it is very important to recognize that protections for genetic information are important for all the reasons that Dr. Collins stated and for one additional reason. Indeed, my genetic information is what it is and if it were published here today, I am not sure I would be too upset about that. But it doesn't just tell anyone looking at it about me, it tells them about my children, as well.

And that is an additional responsibility that I think that I have in not disclosing that information and that anyone that comes across that information has, as well. So that would be, I submit, one additional reason that this particularized, admittedly greater protection for this type of information and other information, that would be one important reason that I would encourage the committee to move this legislation and report it to the Congress. Thank you.

[The prepared statement of Mr. Swain appears at the conclsuion of the hearing.]

Mr. PALLONE. Thank you, Mr. Swain. Ms. Trautwein.

STATEMENT OF JANET TRAUTWEIN, EXECUTIVE VICE PRESIDENT AND CHEIF EXECUTIVE OFFICER, NATIONAL ASSOCIATION OF HEALTH UNDERWRITERS

Ms. TRAUTWEIN. Good afternoon, Chairman Pallone and Ranking Member Deal. My organization is the National Association of Health Underwriters. We are a 20,000 member association of insurance professionals who work with employers and individuals all across America to help them find high quality and affordable health insurance. We do appreciate this opportunity to present in-

formation today on the effect that well-intended genetic discrimination legislation could have on the costs of health insurance, as well as the cost impact on employers who are providing benefits such as health insurance to their employees. We believe that health insurance affordability is the most important component of access to healthcare.

In light of advances in the field of genetic research, some people expressed concern about whether their genetic information might be used improperly to prevent them from obtaining health insurance or by employers for hiring or firing purposes, and I want to emphasize today that NAHU believes that health insurance or employment discrimination based on genetic information of an otherwise healthy individual should be prohibited, provided that the definition of the prohibited information is carefully, clearly and narrowly defined.

We have talked a lot today about HIPAA and I just want to point out a couple of things that I don't think that anyone else has brought up today. HIPAA legislated many new protections for health insurance consumers and among those protections was a provision stating that group health plans cannot consider any individual employee's genetic information in a group setting in the underwriting process unless that genetic information has already resulted in a diagnosis.

We have talked about HIPAA several times today, but primarily from a HIPAA privacy standpoint. And I want to point out that HIPAA has some other very important provisions. One of them is this HIPAA nondiscrimination provision and another one is a HIPAA portability provision and this is one I do want to bring forth. We have heard a lot about the fear factor which greatly concerns me because many of the people who we have been talking about today probably already had insurance and what I heard other people testifying say is that they were concerned that their coverage would be cancelled.

HIPAA portability laws provide for guaranteed renewability of contracts and the things that they are afraid of are already illegal. And so I am concerned that we haven't done a good enough job of educating about that and I am going to take that into consideration, go back to our members about that. I wanted to point that out.

When we talk about people already being subject to nondiscrimination provisions in the group market, unless they already have a diagnosis, what we mean is that if a generally healthy person had some genetic tests run to see whether or not they had markers for a particular illness, that information is already prohibited from use. However, as we have heard earlier, that provision does not apply in the individual health insurance markets and we currently don't have any specific genetic provisions relative to employment discrimination.

Many people at some point in their lives are going to be purchasers in the individual health insurance market and I just want to point out, as Karen said, I did enclose a lot of information about the underwriting process as an addendum to our testimony, only because I want people to understand why it is important relative to the affordability of health insurance coverage. Underwriting in

the individual market is much more difficult for a number of reasons that I have outlined in my written testimony than it is for employer sponsored plans and the ability to use health status in the way that we can use it legally today is very important to keep policies affordable.

In States that have extremely limited the costs or the information that can be used in the underwriting process, the cost of coverage is significantly higher than it is in the States where there is a realistic underwriting process and so I wanted to point out, that is why we care about what this definition is.

Just to move forward, as we look at the issue at hand today, what we want to do is make sure that the information we restrict is really not information that is critical to that underwriting process because using too broad of a definition will prevent normal underwriting procedures. The main issue is what is considered genetic information?

As I stated earlier, HIPAA already prohibits discrimination for any individual within a group in the absence of a diagnosis. And I would like to point out one other thing. During the 108th Congress, Representative Slaughter sponsored H.R. 1910 and that particular bill had some language in it that specifically excluded from the definition of protected genetic information, information about the physical exams of the individual and other information that indicates the current health status of the individual, and this exclusion is not present in the current version of the bill and I would hope that you would consider including that in there because information about current health status is critical to the evaluation of applicants in the individual health insurance market and that information is critical to keeping those policies affordable.

We also would hope, believe that the definition of genetic information should be limited to DNA or related gene testing for the purpose of predicting risk of disease in asymptomatic or undiagnosed individuals and that it should clearly exclude, as it does, such items as age and gender, but an additional exclusion should be information for physical exams and lab work, including items like cholesterol tests that all of us have on a regular basis.

Mr. PALLONE. Ms. Trautwein, again, if you could summarize.

Ms. TRAUTWEIN. I would just summarize by saying that good underwriting is important to affordability of health insurance. The actions that Congress takes relative to this legislation are going to have an impact for many years to come and we are supportive of the concept of this legislation, but we would hope for a few minor adjustments to make this workable so that we don't price people out of health insurance coverage. Thank you.

[The prepared statement of Ms. Trautwein appears at the conclusion of the hearing.]

Mr. PALLONE. Thank you. Again, I would mention to you again that your written testimony is all going to be part of the record. Dr. Hudson.

STATEMENT OF KATHY HUDSON, DIRECTOR, GENETICS AND PUBLIC POLICY CENTER, ASSOCIATE PROFESSOR, DEPARTMENT OF PEDIATRICS, JOHNS HOPKINS UNIVERSITY

Ms. HUDSON. Mr. Chairman, Congressman Deal, Dr. Burgess, I appreciate the opportunity to testify this afternoon and regret that I am the only thing standing between you and happy hour. I might just share my thoughts on H.R. 493 and the results of a survey that we completed this week about Americans' attitudes about genetic testing. You heard from Dr. Collins this morning his incredible enthusiasm about the future of genetic medicine. The American public shares his enthusiasm. In our survey, we found that more than 90 percent of Americans support the use of genetic testing by doctors to identify a person's risk of future disease or to determine a patient's risk of having a bad reaction to a particular medicine.

This enthusiasm extends to genetic research with again, more than 90 percent supporting research use of genetic testing and two-thirds trust researchers to have access to their genetic information. But growing uncertainty and fear threaten public confidence and the future of genetic medicine. More than 90 percent of Americans are concerned that the results of their genetic tests could be used in ways that are harmful to them. As a result, patients may pass up genetic testing that could benefit their health or go to great lengths to keep genetic information out of their medical records and out of insurers' hands.

While people trust their doctors and they trust genetic researchers, they simply do not trust health insurers and employers to safeguard their genetic information. In our survey, 93 percent said that health insurers should not be able to use a person's predictive genetic information to deny or limit insurance or charge higher prices and a similar number said they feel employers should not be able to use this information to make decisions about hiring and promotion. Researchers need to be able to reassure research volunteers their genetic information will not be used to discriminate against them and today researchers can't provide such assurances.

This week I was in Philadelphia conducting focus groups about how ordinary citizens would feel about participating in large population study to understand the genetic, environmental and lifestyle contributors to health and disease. And we heard substantial enthusiasm about this study in hopes that the study would benefit others in the future, but their enthusiasm and altruism was overshadowed by concerns about privacy of genetic information and its misuse.

I want to say just a word about H.R. 493 would affect the conduct of research. The bill would explicitly allow researchers, for the first time, to tell research participants that it is simply against the law for health insurers or employers to use genetic information to discriminate. The impact of this legal change would be substantial. Some are concerned that the mere fact of participation in genetics research could be construed by insurers or employers as indicating a heightened genetic risk and might therefore be used to discriminate them. H.R. 493 would prevent this, as the bill prevents insurers and employers from using information about individuals' re-

ceipt of genetic services. Therefore, participation in genetics research would be protected and could not be used to discriminate.

Turning to the clinical context, some opponents of H.R. 493 have suggested that the bill would make it hard for healthcare providers to collect family history information, to request or recommend genetic testing and to use this information to provide the best possible care. This is simply not the case. H.R. 493 very clearly states that the bill does not limit the ability of healthcare professionals who are providing healthcare to request that a patient undergo a genetic test. Dr. Corwin's example earlier of MammaPrint, he is correct. The plan cannot request or require that the patient take this test because that is really not a plan's role. That is the provider's role.

In conclusion, H.R. 493 prevents the misuse of genetic information while protecting the ability of healthcare providers to collect and use the information that they need to take the very best possible care of their patients. H.R. 493 also protects individuals who participate in research from having their information or even the fact of their participation used in harmful ways. More than three-quarters of the respondents in our survey believe that there should be a law that prevents employers from using results of genetic tests to make decisions and three-quarters also believe there should be a law to prevent insurers from using results from predictive genetic tests to deny or limit insurance or charge higher prices.

The message is clear. The need for Congress to act grows with every new test developed in every patient who decide to forego or delay testing because of discrimination. Thank you for taking up consideration of H.R. 493. And I beat the red light.

[The prepared statement of Ms. Hudson appears at the conclusion of the hearing.]

Mr. PALLONE. You did, indeed, and I thank you for that. Although we are not going to happy hour. I yield myself 5 minutes to ask some questions and I will start with Dr. Corwin.

In your testimony you talk about opportunities to improve the legislation. Specifically, you cite the need to allow health insurance plans to request genetic tests to promote preventative screening and disease management and you also note that Congress should include a more precise definition of genetic information. In my hand here, though, I have a memo which I would like to insert into the record, from the Blue Cross Blue Shield Association to their congressional relations coordinators regarding legislation introduced in the Senate during the 109th Congress, which is identical to the bill before us today.

And this memo states, and I quote, "The definitions of genetic information and genetic tests included in the final bill are narrow and the final version includes insurers and group health plans to use and allows insurers and group health plans to use and disclose genetic information without special consent for treatment, payment and healthcare operations, such as for determining medical necessity, paying claims, detecting fraud and conducting quality management programs." That is the end of the quote.

Mr. PALLONE. Doctor, could you explain to me why you are calling for these changes when it would seem, at least from this memo, that the current provisions of the bill should already sufficiently

address the concerns that you listed? Obviously there is a discrepancy and I would just like you to explain that. I don't know if you have the whole memo, but I think that that section pretty much describes it.

Dr. CORWIN. Thank you for the question. I am obviously not privy to what the Blue Cross memo says.

Mr. PALLONE. Well, you know what? Why don't I give it to you while you are sitting there, but I will be honest with you, that doesn't really add anything from what that paragraph is.

Dr. CORWIN. Our concern is that the health plans be allowed to request tests when they advocate for the better health care of our patients and our members. Health plans design programs on a basis to help address some of the variation that occurs in healthcare. There is a tremendous amount of variations, I am sure you are aware, in healthcare across the country and that that leads to inferior and less competent care in many circumstances.

And as we heard earlier in some of the testimony from Dr. Collins about some of these great tests that are going to be available to us in the very near future, being able to design programs to make sure that our members get the care that they need is going to be very, very critical in terms of helping control these costs and making sure that our members actually get those tests that will help them prevent these unfortunate diseases from progressing.

Be that as it may, that everything is not ideal, the medical care system is not perfect, that people don't always follow up on tests, being able to help direct our membership to those tests and make sure that they get those important follow-up diagnostic examinations on the periodic intervals that are indicated would be very important to health plans.

As the bill is currently worded, our concern is around the fact that it prohibits us from being able to do that at this point in time and deliver evidence-based care or ensure that evidence-based care is given to the patients in a timely fashion. I hope that addresses your question. If it doesn't, I will take this back, take a better read of it and then respond to you off-line.

Mr. PALLONE. Well, you are free. No, I appreciate your response but also feel free to look at that and get back to me, if you like. Thank you. Ms. Pollitz, insurers have testified before that they do not currently ask about genetic information on applications or medical underwriting questionnaires. If that is true, then how do insurers obtain information about an applicant's genetic status?

Ms. POLLITZ. As I mentioned, the underwriting process asks an initial set of questions and about half of applications, the industry tells me, are decided based on how applicants answer those first sets of questions. But the other half of the insurers say I don't know, so a red flag has gone up somewhere and they need to get additional information. Sometimes that is as simple as calling the patient and asking for clarification. You said you are taking this drug; what was the dose, when did you stop? Sometimes it is more in-depth and there is a call to the physician or there is a request for medical records.

Once the records are delivered to the underwriter, even if they didn't ask for the whole thing, even if they just asked for part of it, they are obliged, I mean, they will be fired if they won't, to go

through and read everything that is in that medical record so that they can say that they did a thorough job of evaluating the risks. So when we asked the participating underwriters who worked with us on our study how often or have they ever seen or encountered genetic information in that way, most of them said they had at least once. So they do come across it.

Mr. PALLONE. OK, thank you. I yield to the gentleman from Georgia, Mr. Deal.

Mr. DEAL. Thank you, Mr. Chairman. I want to pick up on the Blue Cross Blue Shield letter that you are talking about. Obviously, this is a comment that this one particular company made with regard to legislation in the last Congress, but they are pointing out parts that they think legislation should include that are important and they referenced it to last year's version.

For example, they point out the definitions of genetic information and genetic tests included in the final bill are now focused on predictive genetic tests and family history. The definitions do not include current health status or information from routine blood tests that are critical for underwriting and et cetera. In that regard, Ms. Terry, my understanding is that your objective is to cover predictive tests that are for the purpose of identifying genetic markers for genetic disease and that it is not your objective to cover genotypes or forensic DNA tests or other markers that are not markers for future disease. Is that correct?

Ms. TERRY. Not exactly. Our intent is to cover genetic information so that it is not misused in insurance or employment.

Mr. DEAL. Well, let us talk about that, then. And maybe you are not the one I have to ask, since you are not the doctor. Let me ask the doctor next to you, then. Doctor, don't we think that at some point there is a correlation between genetic information and being able to treat patients properly?

Dr. CORWIN. Easily answered in a yes. We do believe that there is a need for genetic information to treat people in a predictive way and that would get to the ability to address the preventative measures I talked about earlier.

Ms. TERRY. And also, although I am not a doctor, I do know that, in fact, the bill does allow the practice of medicine that is not impacted and we are talking about insurers and employers.

Mr. DEAL. All right, let us get specific about that, then. And Doctor, that is what I want to ask you. Do you think a doctor can tell a patient that he won't treat that patient unless they undergo a genetic test? And would that be prohibited under this legislation?

Ms. HUDSON. A doctor can request and a doctor can strongly recommend that a patient undergo a genetic test and could decide that it is not medically appropriate to go forward with the specific line of treatment in the absence of that genetic test result. That would be within the practice of a standard practice of medical care.

Mr. DEAL. So there are situations, then, when knowing what the genetic test might show would be important to the treatment of that patient, is that right?

Ms. HUDSON. That is absolutely correct and I think we heard a number of examples this morning of drugs where there are adverse reactions and unless you know what the genotype of the patient is,

the doctor, not the health plan, the doctor needs to know that genetic information before prescribing that medication.

Mr. DEAL. And are you saying, then, that your interpretation is that a doctor can refuse to treat a patient and it be not in a violation of this statute?

Ms. HUDSON. There is no restriction on medical practice, at all, in this bill.

Mr. DEAL. What about if the doctor was an employee of the employer of the patient?

Ms. HUDSON. The rule of construction in the bill, as I read it, does not have any, is not limited by who the employer is of the healthcare provider that is providing the care. The relationship between the provider and the patient is not affected by who employs that particular physician, whether it is an insurance company, whether it is——

Mr. DEAL. My understanding is that that restriction is not in title II. I guess we can clarify that later. Back to Ms. Terry again. If I understand your policy, if a disease has manifested itself, you don't believe that the restrictions in the bill need to apply to genetic information related to that disease, is that right?

Ms. TERRY. So again, what we are looking for is making sure that genetic information is not misused by the employer or the insurer.

Mr. DEAL. You made a distinction in your testimony between manifest and not manifest. So your policy is that we are talking about the not manifest diseases that these tests might disclose, is that right?

Ms. TERRY. So my policy is that when we give examples like MammaPrint or Hepatitis C, et cetera, that those are manifest disease and that in the course of treatment, doctors might, indeed, highly recommend, as Kathy said, a genetic test and that is certainly part of the usual course of medicine.

Mr. DEAL. OK. Mr. Fishman, let me ask you this. As you read this bill, does it focus on discriminatory misuse of genetic information or does the language focus more on the flow of information?

Mr. FISHMAN. Well, one of our concerns is, I hope and I guess I failed to articulate properly, is that it seems to us, it seems to my coalition and to me, personally, that the focus of this bill is, in fact, not on the misuse of information or the discriminatory use of information, it is on the acquisition, including the innocent acquisition, and the flow of that information. I think that, inevitably, any bill that is directed at the flow of information rather than the abusive use of the information, inevitably will have unintended consequences and we have heard of a couple.

I have tried to identify a couple. I think Dr. Corwin has identified a couple. I think that the purposes of this bill and the goals of this bill can be achieved if you direct your attention to the conduct that you wish to prohibit, rather than hope that people who have hundreds of motives will or will not take tests, may or may not take tests, will or will not have insurance. This committee and this Congress should focus on the abusive conduct that you wish to penalize and make that the focus of the bill.

Mr. PALLONE. Thank you, Mr. Deal. Dr. Burgess.

Mr. BURGESS. Mr. Fishman, perhaps you could continue with that line for just a moment, because I am concerned about the unintended consequences. I do think that some protections are necessary. I think the promise of genomic medicine is enormous and will benefit, perhaps not those of us in our generation, but certainly, our children and our children's children, and we want to be certain that it is done correctly, so could you detail for me a little bit more, flesh that out a little bit more about what you are concerned about?

Mr. FISHMAN. Well, I will try to. I think that many of my colleagues on this end of the prior panel's over-expansive in their denials about what this bill covers. I think the bill is, I think the definition is over-expansive and I think some of the exclusions are under-exclusive. For example, in section 210 there is a provision that attempts to exclude manifest ailments from the reach of this bill, but it says that only medical information that is not genetic information can be disclosed.

So we have the bizarre situation of let us say, a company nurse who is treating someone who has collapsed and during the triage, would say oh, it is probably my heart because my dad had a heart problem, too. Under GINA and because she has now just learned family history, which is genetic information, that nurse could possibly tell a treating physician I have a patient who has collapsed but could not say oh, by the way, it may be a heart problem because his dad had a problem. And that is simply a drafting problem that I think comes from over-inclusiveness because the direction of the bill is directed at the flow of information rather than the abusive use of the information.

That is one of the reasons that my oral testimony and a good deal of my written testimony is devoted to thinking about including, as part of the text of this statute, the exceptions and exclusions that are included in the HIPAA regs for the privacy parts where treatment is the first exception under HIPAA where there should be an exception for treatment. That nurse should not have to wonder whether the mere utterance of oh yes, I know that his dad had a heart attack is a potential problem that could lead to a jury trial and punitive damages under the enforcement scale of title II.

I mentioned in my oral testimony the definition of a disease that occurs in a family member that is not an inheritable disease, that is not an asymptomatic disease, that is not even a disease that is genetically related. There ought to be some focus on what the purpose, what is the goal of the bill? You have heard my co-panelists talk about discrimination in insurance and employment. You haven't heard of a single employment discrimination case but one and yet, we are going to have an entire legislative scheme devoted to what nobody has yet been able to demonstrate even exists.

My clients, large and small, have difficulty finding employees who can do the job and can come to work regularly, they don't particularly care much about your genomes. Most of them don't even know what it is and I am one of them. Let us focus on the abusive conduct and craft a bill that is narrowly directed to achieve the goal that we all share, which is nondiscrimination in employment

and insurance and let us not focus on our hopes and our prayers for how medicine can develop in 2030.

Mr. BURGESS. I thank you for your candor. Dr. Corwin, I was particularly intrigued by the comments you had for improvements to 493, and under one of the bullet points that medically indicated testing should be encouraged to promote consumer access to appropriate coverage and treatment. And I think we heard from someone else on the panel that these are decisions that actually should be made by the doctor, not the insurance company. Would you care to expound upon that?

Dr. CORWIN. Thank you very much. It is a great question. From my perspective, and with all due respect to my colleague, I would disagree with her on that point. I think that health plans do have a role for requesting and requiring certain genetic testing to be done for the purpose of treatment. With all due respect to all my colleagues, there are times that evidence-based medicine is not practiced in a timely way and if we know that individuals are going to need pharmacogenomic testing for the purpose of delivering the best possible care to them and to be able to decide what is the best possible chemotherapeutic protocol for non-small cell lung cancer, which is a devastating disease, and within a very short period of time, we will have this type of genomic information available to help decide what is the best possible test. It is not inappropriate for the plans to be able to request that kind of testing to be done to ensure that the patient gets the best possible care. If it is not done, one is using the best guess scenario once again. I would hope that in every case that wouldn't be necessary, but in some cases, it may be.

Mr. BURGESS. Well, I always resented it when insurance companies would challenge my clinical acumen, but it was probably appropriate in other doctors' cases.

Dr. CORWIN. I would totally agree.

Mr. BURGESS. Well, I think you referenced somewhere in here the Cytochrome people are, as being another area where this may have some applicability.

Dr. CORWIN. In Dr. Collins' example about the leukemic children, that is very true and it is also going to be true for a number of other drugs, specifically some of the newer antimicrobial agents that are being developed for fighting infections will not work as well in some people, but will work extra well in other people and dosage adjustments will become much more difficult without having testing ahead of time and having that information available, so it would be appropriate to require that kind of testing in those situations.

Mr. BURGESS. Thank you. Once again, Mr. Chairman, just reserve the right to submit written questions.

Mr. PALLONE. We are also going to do a second round now, so if you want to stay, you can ask questions again. I will yield to myself for 5 minutes. I don't know if I will use the whole five, but I just wanted to ask Ms. Trautwein a question. We heard, in Dr. Corwin's testimony that AHIP does not oppose GINA and I am just curious to know whether or not NAHU supports or opposes the enactment of GINA.

Ms. TRAUTWEIN. Well, that is a great question. I was very curious about the Blue Cross letter, because we actually worked very closely with the people on the Senate side, as well, coming to the language that was there. Sometimes on the other side things are a little different than they are over here.

Mr. PALLONE. That is for sure.

Ms. TRAUTWEIN. And I think that many of us thought that that possibly might have been the best thing that we could get out of there rather than coming up with something worse, so I would just state that for the record. Now, relative to the consideration over here, I think you guys might be able to improve on their work a little bit. And I think it is not broad-scale adjustments we are talking about. Some minor adjustments to the definitions could make this a truly good piece of legislation. And so I would say that we support it with a few caveats there, that we think that you could make it a little bit better and you have an opportunity to do that and I would hope that you will.

Mr. PALLONE. Thank you. Ms. Pollitz, is providing healthcare limited by this bill, as Mr. Fishman seemed to suggest? If you would just comment on that.

Ms. POLLITZ. Actually, I think Dr. Hudson was correct, that the bill doesn't limit the way physicians practice medicine and it doesn't even prohibit health insurers from asking about the results of a genetic test. It just says that a health insurer can't tell a patient to undergo a genetic test. Dr. Collins talked about the six P's of genetic testing and you could add profound to that. I think this is an incredibly personal and profound decision to undergo genetic testing and people may not want to. Not just because they fear it, they may not want to for other reasons and if they don't there may be other consequences that come from that and we have heard about them today, that they may be foregoing treatment options and so forth, but nobody can tell somebody to take a test. Doctors can recommend it, but the health plans need to stay out of that. They can ask, for purposes of medical appropriateness review and so forth, if a test was taken, what was the result, but they can't force a patient to take a test.

Mr. PALLONE. OK, thank you. I wanted to go back to Dr. Hudson, actually, and ask if Congress failed to take action on genetic nondiscrimination legislation, how do you believe scientific research would suffer as a result? In other words, if Congress were able to pass this legislation, how do you believe scientific research would benefit?

Ms. HUDSON. We are at a stage now where we can do the research to uncover those weak genetic contributors that are interacting with environmental factors and with lifestyle factors to common diseases, which you really haven't had the power to explore before and in order to do that, we are going to have to do massive studies that include hundreds of thousands of people who actively participate and share not only their genetic information, but their environmental exposures, their lifestyles, et cetera. That is sort of the next big push in medicine and medical research and if we don't pass this bill, we won't get people to sign up and we won't understand how genes and environment and lifestyle work together and how we can intervene to reduce our risks of disease.

Mr. PALLONE. OK, thank you. And then from your survey data, it is clear that the public is concerned about who has access to their genetic information, but in terms of protections from genetic discrimination, what do you think the public expects and wants and do you think that that this bill will address those concerns?

Ms. HUDSON. I think the public clearly wants legal protections at the Federal level against misuse of genetic information and I disagree with some of my colleagues here. I think that the bill does include very specific and concise prohibitions on the use of genetic information, not just how it travels, but how it is actually used and I think those are appropriate restrictions on the use of genetic information both in title I and in title II. I think we are going to have a very big job ahead of us when this bill passes and I believe it will pass. When this bill passes, we have a very big job to then educate the American public that they are now protected and they can, with confidence, take a genetic test that is appropriate for them or participate in biomedical research. There is a lot of suspicion out there that we will have to overcome with the right information about the protections that will be put in place by H.R. 493.

Mr. PALLONE. Thank you. Mr. Deal.

Mr. DEAL. Thank you. The reason I think some of us are asking very specific questions is that this is the kind of legislation that has profound consequences and many times the direct opposite consequences of what was intended by the legislation, if it is not carefully crafted, and that is the reason that some of the questions that I am asking and others are asking are being posed. And let me just take a few more shots at it. I am looking at a chart comparing permitted uses and disclosures under HIPAA rules versus the same thing under this legislation and some of it goes directly to the issues we have already talked about. HIPAA, for example, has a business associates disclosure permission.

It says it has to be related to the delivery of the health functions. It has an exception for treatment, payment, healthcare operations. We don't see a similar provision in this legislation. So I guess my question would be am I correct that the 202(c) appears to say that even if you are providing a health service, you are still subject to the prohibitions of section 206(b) and if so aren't we creating a huge problem if there is no treatment or operations exception built into this legislation like is built into HIPAA? Mr. Fishman, this is sort of a lawyer's question, I guess.

Mr. FISHMAN. I am not sure it is, but I will give it a shot. I think it is correct and that is really the core of my testimony this afternoon. It is an odd situation that I find myself in. My clients don't collect this information and they don't use this information. There is no evidence that they even care about this information. But they are going to be included in a privacy regimen that is both, we think, over-inclusive and needlessly burdensome and seems to ignore the highly reticulated privacy program that the HIPAA regulations created after months of regulatory oversight with reams of public comment.

I cannot, for the life of me, understand why this committee or why this lobby would want to ignore the kind of effort that HHS underwent to learn, from public comment and from survey of the very same people that you are trying to include here, and not in-

clude the kinds of learning that they discovered would make HIPAA, the HIPAA privacy regs, meaningful and useful. For my purposes, and as I said, this is almost tangential, because my clients, members of my coalition, don't gather genetic information, don't do genetic testing, don't use genetic information in employment decisions and don't want to.

But it seems we are going to get dragged into a privacy regimen that is additional to the one they spent about $10 billion and a hundred million hours trying to learn. It is highly, highly structured, it is highly directed to meet particularized needs and for the life of me, I, as someone who used to be in a regulatory agency, I can't understand why this body wouldn't want to use the benefits of all of the efforts and all of the learning that HHS has proffered in creating the HIPAA regs.

Mr. DEAL. Back to the specific, a doctor who is employed, is he under the prohibitions that you read into this bill?

Mr. FISHMAN. As I said, in 210, I hope it is a drafting error and all I can do, like most of you folks, I live in an imperfect world and I can't make the language that I read into something other than what I honestly read. In 210 there is an exception that is supposed to be for medical information that is not genetic information, which means, to me, that genetic information is still regulated and if I am a doctor employed by an employer covered by GINA, I have to be concerned with whether the information I am relating, even for treatment purposes, to another physician or to anyone else, is included as regulated in 210. And if it is regulated in 210 and I violate it, I am in the enforcement soup of title VII, which is what you have included in this bill. I don't think that is what you intended. I hope you can correct it, but as currently drafted in this imperfect world, that is what I read.

Mr. DEAL. Thank you, Mr. Chairman.

Mr. PALLONE. Thank you. Dr. Burgess.

Mr. BURGESS. Well, Mr. Fishman, let me just ask you. The Mayo Clinic, for example, where all of the doctors are not independent contractors, they are employees of the Mayo Clinic system, would that system be at risk in what you are concerned about in 210?

Mr. FISHMAN. Well, it is not only that. One of the members of our coalition is CUPA HO, which is "College and University Professional Association." That means all of those medical schools and all of those universities, they are included, too, and have to face this problem. It may not be a problem if they don't convey the information, but if they do convey the information, why would you want to introduce the possibility of raising that doubt and causing that delay? Why isn't the exception here the same as PTO in HIPAA?

Why would you even want a physician at the Mayo Clinic or at the University of Texas to have to worry about wait a minute, I now know genetic information. This exclusion, which appears to be intended to help me treat manifest ailments, it is not that I am only covered for medical information that is not genetic information. Why should that poor person have to pause, to hesitate to try to figure this out when it seems that it was not the intent of Congress to want to cover that sort of a situation. And that is where I am. I am not a physician, two doctorates, but neither one in medicine, so there I am.

Mr. BURGESS. Well, and I thank you for your frankness and your candor. I was on the outside looking in when Congress, in '96 or '97 passed, as part of the Health Insurance Portability and Accountability Act, what we now know as the HIPAA privacy regulations. It seems like it was a fairly short section of that Kennedy-Kassebaum bill and many years later delivered to my doorstep, was an enormous cost compliance that didn't seem to do a whole lot to further patient care. I never felt like I was the problem in the first case.

Mr. FISHMAN. Well, I think there are something like 1,275 pages of HIPAA regs, so you are not responsible for that.

Mr. BURGESS. I do understand why you are concerned about what would seem to be a fairly narrow provision in this and in the field of unintended consequences and I know we have gone a long time today, Mr. Chairman. I see you holding your forehead and I am sensitive to that fact and I appreciate the fact that we can submit written questions, but Ms. Trautwein, before we finish up today, you mentioned concern about affordability of health insurance and I will just tell you that that is the one thing that is always on my mind, the decisions we make here, are they helpful or hurtful as far as the average middle class family affording their health insurance. Do you have some further thoughts on that?

I remember when this, and I wasn't here when this body went through the discussion of patient bill of rights, but I do remember hearing about the for every dollar cost increase there is, we knock so many people off of the rolls of the insured. Do you have any thoughts about what the effect of this legislation will be?

Ms. TRAUTWEIN. Well, I think if we make some needed changes, it is not going to impact things too much at all, other than to provide some protections that are obviously needed. I think we do need to look at the definitions that are there because right now they are broad and I am very concerned that a regulator, some point down the road, people who would be under compliance with this would not be clear on what it was that they were or were not supposed to do and what Congress intended. And so my suggestion is that we just get really clear and very specific on what is and is not protected information and don't leave it to someone else to figure out. Let us be specific. If we don't mean current health status, let us say that. If we don't mean routine exams and lab work, let us say exactly what we mean and that way we can underwrite appropriately and particularly in the individual health insurance market, given what we have today and given what Karen Pollitz said, that things will change; of course they will, but right now, we don't want to price people out of coverage now and create a problem that is much worse than what we started with by causing many more people to become uninsured because they are priced out of coverage. And so I think we can do this, we can tighten this up and make it better, but I think it needs a little bit of work.

Mr. BURGESS. Well, Mr. Chairman, I am going to surprise you and yield back 16 seconds. I do thank the panel for their forbearance today. I know it has been a long day, but this is important legislation and I appreciate you all participating.

Mr. PALLONE. Thank you very much. I want to thank all of you. I thought it was very thoughtful and useful discussion today, so I

really thank you. It really wasn't that long, it was just because we had the hour that we were voting, I think. Let me just remind the Members that you may submit additional questions for the record to be answered by the relevant witnesses and they should be submitted to the committee clerk within the next 10 days. And without objection, this meeting of the subcommittee is adjourned. Thank you, everyone.

[Whereupon, at 5:20 p.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

Testimony
Before the
Subcommittee on Health
Committee on Energy and Commerce
United States House of Representatives

The Threat of Genetic Discrimination to the Promise of Personalized Medicine

Statement of
Francis Collins, M.D., Ph.D.
Director
National Human Genome Research Institute
National Institutes of Health
U.S. Department of Health and Human Services

For Release on Delivery
Expected at 1:00 p.m.
Thursday, March 8, 2007

Good afternoon, Chairman Pallone and members of the Subcommittee. Thank you for the opportunity to speak with you today. I am Francis Collins, Director of the National Human Genome Research Institute (NHGRI) at NIH, part of the National Institutes of Health (NIH) within the Department of Health and Human Services.

It is my pleasure to be appearing before you today as you consider the Genetic Information Nondiscrimination Act of 2007. We stand at a critical time in the development of medicine: the mapping of the human genome has provided powerful new tools to understand the genetic basis of disease, but our ability to fully realize the promise of personalized medicine is limited by legitimate fear of how this powerful information could be abused. Many people are afraid that their genetic information will be used against them and are unwilling to participate in medical research or be tested clinically, even when they are at substantial risk for serious disease. More than ten years ago, expert advisors to the genome project concluded that federal legislation is needed to provide all Americans with protection against genetic discrimination in health insurance and employment. Without it, we may never realize the full potential of genomic research, and, more importantly, of individualized approaches to health care.

New Tools and Technologies

Since the completion of the Human Genome Project (HGP) in 2003, major advances in our understandings of the causes of disease have been appearing at an accelerated pace. As one example, the HGP enabled the development of the "HapMap," a detailed map of variations in the spelling of our DNA instruction books. Research supported by NHGRI has also led to orders of magnitude reduction in the costs of sequencing an individual's complete genome for medical

purposes. It is the vision of NHGRI that within the next ten years, the cost of sequencing the complete genome of an individual will be $1,000 or less. Should an individual so choose, this information could then be used as part of routine medical care, providing health care professionals with a more accurate means to predict disease, personalize treatment, and preempt the occurrence of illness.

New Findings in Genetics of Common Disease

Even before the $1000 genome becomes a reality, advances from genome research are already leading to important new understanding of the role of genetic factors in a number of common diseases. For instance, the HapMap made possible research that recently identified two major genes that influence risk for developing adult macular degeneration, a leading cause of vision loss in the elderly, with those at lowest risk having less than 1% chance of developing the disease, and those at highest risk a 50% chance. Other similarly derived recent discoveries include identification of variants in different genes that elevate risk for developing type 2 diabetes, Crohn's disease, prostate cancer, and Alzheimer's disease. Other new findings include the identification of genetic variants that predict whether or not a particular individual will respond well to drug treatment for disease, or will suffer a side effect. Each of these discoveries opens a new path toward diagnosis, prevention, and treatment, but the public will be reluctant to travel these paths if fair and reasonable protections against the improper use of genetic information are not in place.

NHGRI is currently involved in other groundbreaking initiatives, such as the Genetic Association Information Network (GAIN) and the Genes, Environment, and Health Initiative

(GEHI), that will accelerate understanding of the environmental and genetic causes of common diseases such as asthma, schizophrenia, cancer, bipolar disease, diabetes, and Alzheimer's disease. Increased understanding will in turn lead to better strategies for individualized prevention and treatment and enable the development of personalized health care. NHGRI has also joined with NIH's National Cancer Institute in funding a joint project called The Cancer Genome Atlas (TCGA) to accelerate understanding of the molecular basis of cancer through application of genome analysis technologies. TCGA will provide new insights into the biological basis of cancer, and will help to optimize treatment and prevention strategies.

Already, healthcare providers can test whether some of us carry DNA variants that pre-dispose us to certain diseases, and new research efforts could help to expand this capability and possibly offer better opportunities for preventive measures. If illness does occur, doctors will have more powerful tools to identify the molecular causes, and to prescribe medicines based on individualized genetic information. This is our chance to transform medicine from "one-size-fits-all" to a potentially personalized approach.

Fear of Discrimination

As you can see, the science of genomic medicine is rocketing forward. But fear of genetic discrimination threatens to slow both the advance of such groundbreaking biomedical research and the integration of the fruits of that research into our nation's health care. If individuals continue to worry that they will be denied health insurance or refused employment because they have a predisposition to a particular disease, they may forego genetic testing that could help guide medical professionals to lessen their risk, simply because the test identifies them as having

such a predisposition. This is about all of us, as there are no perfect specimens at the DNA level; each one of us carries numerous gene variants that increase our risk of developing one disease or another. Therefore, each one of us is at risk for genetic discrimination.

Public concerns about the possible misuse of their genetic information by insurers or employers have been documented. A recent NIH study of families at risk for hereditary nonpolyposis colorectal cancer (HNPCC) (a particular form of colon cancer) revealed that the number one concern expressed by participants regarding genetic testing was about losing health insurance, should the knowledge of their genetic test result be divulged or fall into the "wrong hands." Nearly half of individuals with a 50% chance of having the HNPCC mutation cited fear of insurance discrimination as their greatest concern surrounding their participation in this study. Similarly, a recent survey of the personal attitudes of cancer genetics specialists showed that 68% of respondents would not bill their own insurance company for HNPCC or breast and ovarian cancer (BRCA) genetic testing due to fear of genetic discrimination, and 26% of respondents said they would use an alias when being tested.

NHGRI remains deeply concerned about the impact of potential genetic discrimination on both research and clinical practice. Unless Americans are convinced that their genetic information will not be used against them, the era of personalized medicine may never come to pass. The result would be a continuation of the current one-size-fits-all medicine, ignoring the abundant scientific evidence that the genetic differences among people help explain why some of us benefit from a therapy while others do not, and why some of us suffer severe adverse effects from a medication, while others do not.

In 2005, the Bush Administration issued a Statement of Administrative Policy supporting Senate passage of S. 306, the "Genetic Information Nondiscrimination Act of 2005." That bill never came to a vote in the House. In January of this year, the President visited the NIH and again called on Congress to pass a bill to protect Americans from genetic discrimination. We share the President's concern and commitment to this issue, and we are delighted to see this issue being taken up early in the 110th Congress. We are hopeful that this will be the year when the American people are given a gift that is long overdue – federal legislative protection against genetic discrimination.

Thank you, Mr. Chairman. I would be pleased to answer any questions that the Committee might have.

Testimony
Before the Subcommittee on Health
Committee on Energy and Commerce
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Statement of

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Introduction

Mr. Chairman and members of Committee, I am Susan McAndrew, Deputy Director for Health Information Privacy, in the Office for Civil Rights (OCR) at the U.S. Department of Health and Human Services (HHS). OCR is responsible for the administration and enforcement of the Privacy Rule, issued pursuant to the Health Insurance Portability and Accountability Act of 1996 (HIPAA). On behalf of Winston Wilkinson, the Director of OCR, I thank you for the invitation to testify today on the role of the Privacy Rule in the protection of genetic information held by those health plans and health care providers that are covered by the Rule.

Background

The *Standards for Privacy of Individually Identifiable Health Information* – better known as the HIPAA Privacy Rule – establishes, for the first time, a set of national standards for the protection of certain health information. In December 2000, HHS issued the Privacy Rule to implement the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Those regulations were modified in a number of significant ways by further rulemaking in August 2002 to ensure the final Privacy Rule was workable and to avoid unintended consequences of certain provisions that would have impeded an individual's access to health care or prompt payment for those health care services. These federal privacy standards have been in operation for almost four years, and we are pleased to note that significant progress is being made to embed these privacy principles into the daily practices of health plans and health care providers across the nation.

The Privacy Rule standards address the use and disclosure of certain health information that is individually identifiable – called protected health information – by persons or entities that are subject to the HIPAA requirements – called covered entities. It is important to remember that the HIPAA Privacy Rule only directly applies to persons or entities that are defined as "covered entities," including health plans, health care clearinghouses, and any health care provider that electronically transmits health information in connection with a transaction – such as billing a health plan for reimbursement for services – for which there is a HIPAA standard transaction and code set. The Privacy Rule standards also give individuals certain rights with respect to their health information, including the right to receive notice from a covered entity about that entity's privacy responsibilities and practices and about the individual's other rights under the HIPAA Privacy Rule; the right to access and get a copy of their medical record; the right to have that record amended if it is incomplete or incorrect; and the right to request an accounting from the covered entity of certain disclosures of protected health information. The HIPAA Privacy Rule creates a uniform federal floor of privacy protections for health information; however, it does not prevent states or entities from adopting laws or practices that provide additional privacy protections.

The Privacy Rule is carefully balanced to ensure strong privacy protections without impeding the flow of information necessary to provide access to quality health care, and to that end, the Rule permits covered entities to share protected health information for core purposes – to treat the individual and to obtain payment for the health care service provided – without obtaining the individual's prior consent or authorization. The Privacy Rule also permits other uses and

disclosures of protected health information without an individual's authorization, including uses and disclosures necessary for the normal business operations of health plans and providers, as well as a limited number of public interest disclosures where identifiable health information is needed for these purposes. For example, and subject to specific conditions or limitations, a covered entity may, without individual authorization, disclose protected health information as required by other federal or state law, for public health purposes, or to permit health oversight agencies to carry out their functions. And, of course, the individual may authorize in writing any other use or disclosure of protected health information. The Rule establishes standards to make sure that individuals' authorizations for particular uses or disclosures of protected health information are both informed and voluntary.

Key Privacy Rule Provisions for Genetic Information

With this general background, I would like to turn to the specific provisions of the HIPAA Privacy Rule that will have the most direct impact on how genetic information is protected and the circumstances that permit a covered entity to share such information with others.

Genetic Information as Protected Health Information

The HIPAA Privacy Rule protects certain individually identifiable health information that is held by a covered entity or its business associate. Individually identifiable genetic information that is obtained by a covered health care provider or health plan is therefore subject to the protection of

the HIPAA Privacy Rule. As indicated above, the Privacy Rule provides a federal baseline of protection for all protected health information, including genetic information.

With very limited exceptions that are not relevant to the protection of genetic information, the Rule does not differentiate among the identifiable health information protected – that is, it does not classify some protected health information as "sensitive" or provide heightened protections for these types of information. The Privacy Rule does, however, preserve state or other law that may provide more stringent privacy protections for particular types of health information. Therefore, state laws that provide additional privacy protections for genetic information remain in effect.

Permitted Uses and Disclosures of Protected Health Information by Health Plans

The Privacy Rule standards control how health plans – as covered entities under HIPAA – may use or disclose protected health information, including genetic information. The Privacy Rule recognizes payment for health care services as a core function, and permits the use and disclosure of protected health information without individual authorization for payment purposes, along with the health care operation activities necessary to support this function. These core functions allow a health plan to use or disclose protected health information as necessary to determine or fulfill its responsibilities for coverage and provision of benefits under the health plan, and to provide payment or reimbursement for health care services provided to individuals. Among the activities included in the payment function are determinations of eligibility or coverage, risk adjusting, billing and claims management, collection of premiums,

and utilization review activities. In addition, health plans may, with some additional limitations on the recipient of such information, use or disclose protected health information for underwriting, premium rating, or other activities related to the creation, renewal or replacement of a contract of health insurance. When using or disclosing protected health information for these payment or health care operations purposes, or when requesting protected health information from another covered entity, the health plan must make reasonable efforts to use, disclose or request only such information as is minimally necessary to accomplish the intended purpose.

In general, under the Privacy Rule, a health plan is not permitted to require the individual to sign an authorization for the release of protected health information as a condition payment, enrollment in or eligibility for benefits under a health plan. However, the Rule does allow health plans to condition enrollment in or eligibility for benefits under the plan on obtaining an individual's authorization, if it is requested by the plan prior to the individual's enrollment. The authorization must limit the health information sought to that needed for an enrollment or eligibility determination for that individual or for its underwriting or risk rating determinations. Thus, under the HIPAA Privacy Rule, protected health information, including genetic information, could be requested by the plan for enrollment, eligibility or underwriting purposes and used by the plan in making these determinations today.

While beyond the scope of my testimony here today, I should note that other laws exist to protect the use of genetic information for health insurance purposes. For example, HIPAA Title I prohibits discrimination in enrollment and eligibility for benefits in group health plans based on

health status, including genetic information. HIPAA Title I also prohibits increasing premiums or contribution rates of an individual in a group health plan based on health status, including his or her genetic information. Further, HIPAA Title I prohibits group health plans and group health insurance issuers from using genetic information – in the absence of a diagnosis of a condition related to that genetic information – as the basis for a "preexisting condition exclusion."

It is important to remember that the Privacy Rule is concerned with maintaining the confidentiality of individually identifiable health information provided to health care providers and health plans without impeding the ability of providers and plans to efficiently and effectively deliver high quality health care and pay for that care. The Privacy Rule does not seek to regulate the health insurance industry or the conditions or terms for the provision of coverage for health insurance. Thus, the Privacy Rule does not specifically limit how a health plan may use or disclose genetic information in its enrollment or underwriting activities, but would treat such information as any other protected health information needed for these core functions.

Disclosures of Protected Health Information to Employers

Just as the HIPAA Privacy Rule does not seek to regulate the provision of health insurance, the HIPAA statute does not permit the regulation of employers in general, or the employment functions of covered entities. A business is not a covered entity under the HIPAA Privacy Rule simply by virtue of being an employer. The Department understands that covered health insurance issuers and health care providers are also employers, and, thus, may have obtained individually identifiable health information about their employees both in their health care

capacities and in their employment capacities. To avoid potential confusion, the HIPAA Privacy Rule was amended in 2002 to expressly exclude from the definition of "protected health information" an employee's individually identifiable health information in the employment records held by a covered entity in its role as an employer.

To illustrate this distinction, the medical record of a hospital employee who is receiving treatment at the hospital is protected health information and is covered by the Privacy Rule. The hospital may use that information, including genetic information, only as permitted by the Privacy Rule, and in most cases will need the employee's authorization to access or use the information in the medical record for employment purposes. When employees give their medical information to the covered entity as the employer, such as when submitting a doctor's statement to document sick leave, or when the covered entity as employer obtains the employee's written authorization to obtain protected health information (which may include protected health information held by the employer in its capacity as a covered health care provider under HIPAA), such as an authorization to disclose the results of a fitness for duty examination, that health information becomes part of the employment record, and as such, is no longer protected health information under the HIPAA Privacy Rule. The employers' obligations with respect to employee health information contained in employment records of the employer are governed by other law on employment practices, such as the Americans with Disabilities Act, not the HIPAA Privacy Rule.

The Privacy Rule does address another employer role – that is, as the sponsor of a group health plan. Again, the Rule does not generally regulate the employer's duties or functions as a plan

sponsor, but rather determines when the group health plan – as the HIPAA covered entity – may disclose protected health information to the employer. The Privacy Rule permits the disclosure of summary health information to the plan sponsor for obtaining premium bids or for modifying, amending or terminating the group health plan, and allows the sharing of individual information on enrollment or disenrollment in the group health plan. Otherwise, the Privacy Rule restricts disclosures of protected health information, including genetic information, by the group health plan to the plan sponsor to those purposes set forth in the plan documents. Importantly, the Rule requires that the plan documents specify that the plan sponsor may not use such information for any employment related decisions. The Privacy Rule, however, does not, and cannot, restrict employment actions with respect to genetic information received by an employer directly from the employee or by virtue of a written authorization from the employee.

Closing

I trust this information will be helpful to the Committee in furthering its consideration of legislation to protect genetic information from discriminatory uses in the health insurance and employment arenas. The Department favors enactment of legislation to prohibit the improper use of genetic information in health insurance and employment, and, as you can see from my testimony, the HIPAA Privacy Rule provides an important federal baseline of protection for all protected health information, including genetic information. For additional information on Privacy Rule, the Office for Civil Rights HIPAA Privacy web site at http://www.hhs.gov/ocr/hipaa, contains the full regulatory text, as well as useful summaries of the Rule and answers to over 200 frequently asked questions.

Again, we welcome the opportunity to explain how the HIPAA Privacy Rule operates to protect an individual's health information, without impeding or delaying the delivery of health care. Mr. Chairman, this completes my prepared remarks and I will gladly answer any questions you or other members of the Committee may have at this time.

Testimony of

Sharon F. Terry
President and CEO, Genetic Alliance
Chair, Coalition for Genetic Fairness

Energy and Commerce Committee
Subcommittee on Health
March 8, 2007

Sharon Terry, Coalition for Genetic Fairness

Chairman Pallone, Representative Deal, and Members of the Subcommittee, thank you for bringing us to this moment and for the opportunity to testify here. Representatives Slaughter, Biggert, Eshoo and Walden demonstrate robust vision and courage to introduce again the legislation that will make it possible for Americans to benefit from new genetic tests and technologies.

My name is Sharon Terry and I represent millions of Americans affected by genetic conditions.

I am president and CEO of Genetic Alliance, a coalition of more than 600 disease support groups, and I am chair of the Coalition for Genetic Fairness. Mine is not a chosen profession, it is a vocation thrust upon me when my children were diagnosed with a genetic condition that will rob them of their vision in the prime of their life. Quite poignantly, the Genetic Information Nondiscrimination Act of 2007 will not protect my children, or the millions I officially represent. They all have manifested disease, and this bill, appropriately, does not protect them. This is a critical point often obscured in many of the arguments against the legislation. This bill is not about those who already have signs or symptoms of disease, but rather about those who carry a genetic mutation, which increases their chances to develop a disease or condition. This is a critical point often obscured in many of the arguments against the legislation.

Though I do not personally benefit, I have worked on this legislation for 12 years, since Chairwoman Slaughter first introduced it. With others present here, I founded the Coalition for Genetic Fairness to support this legislation – and we have had a long and uphill battle. We are several hundred organizations strong and include members from every sector of society – disease support groups like Facing Our Risk of Cancer Empowered; healthcare professional organizations like the American Society of Human Genetics, National Society of Genetic Counselors, and American Academy of Pediatrics; women's leadership groups like Hadassah, The Women's Zionist Organization of America, labor groups such as the National Workrights Institute, academia like Brown University; and most significantly, companies like Affymetrix, IBM, and 20th Century Fox. We thank them and those of you, who year after year, supported this legislation and are impatient to see it pass. We have compromised and conceded a great deal during these years, and we believe that the bill before you is fair and well balanced.

The faces and the voices of the hundreds of individuals who have contacted us, fearing for their children, their families, their jobs, their insurance, have fueled my passion for more than a decade. Men, women, and children – families from communities all across this country – have told us their stories and in some cases, pleaded for us to help them.

In 2003, Heidi Williams of Kentucky called me when her children were denied individual health insurance from Humana, Inc. Heidi has alpha-1 antitrypsin deficiency, an autosomal recessive genetic disease. Humana rejected the children's application stating that since the children were carriers of alpha-1 antitrypsin, Humana could not cover them. With our help, Heidi explained in an appeal that carriers of genetic conditions are not

affected by the condition, but Humana again denied her children health insurance. I then called a reporter from a prominent national newspaper and told her Heidi's story. The reporter called Humana and Heidi received notice of retroactive coverage late that same night. This year, Heidi's daughter Jayme Williams wrote this letter to her congressman:

> Dear Congressman Ron Lewis,
>
> My name is Jayme Williams, and I am in the fifth grade and live in Cecilia, Kentucky. My brother and I are carriers of Alpha-1 Antitrypsin Deficiency, a defective gene in our DNA that can be passed on to our future children. While my brother and I both have only one defective gene, my mother was given two, one by her mother and one by her father. The two genes make my mother's lungs very sick. My brother and I were denied health insurance because we carry mutations in the Alpha-1 gene.
>
> My mom tells our story because other people are too afraid to tell theirs. Discrimination makes people very afraid. When people are discriminated against, they are sometimes told they will lose something they need if they speak out against the people causing the discrimination.
>
> I think you should support the bill that is before the House of Representatives that would make it illegal for anyone to do this to another person in the USA. My mom says that everyone is created equal, and deserves to be treated fairly. Please help my mom stop people from treating others unfairly.
>
> Sincerely,
> Jayme Williams

Let resonate these heart-felt words from a young girl who cannot imagine that carrying a mutation in a gene makes her uninsurable. I assured her that we would continue to work hard so that she and others like her are not discriminated against again.

I am also reminded of Becky Fisher, who shares a mutation for inherited breast cancer with many in her family. Having watched her mother, aunts, and cousins die of breast cancer, and she herself surviving cancer, she thinks only of her daughter, who was brave enough to be tested, and says of her:

> One of the not-so-good things is that having a documented genetic mutation makes her vulnerable to more than just a devastating illness: she also faces the heavy burden of never knowing whether or when she will legally be asked to take a genetic test as a condition of employment, be lawfully fired from a job because of the high cost of her potential medical care, or be legitimately denied health insurance on the basis of her genetic predisposition to disease.

We are all Heidi and Becky's children; we all carry mutations for dozens of diseases, and we are all vulnerable. Aren't health and disease enough to worry about? We cannot afford to also worry about discrimination based on these mutations, silent mutations, with no signs or symptoms. This is simply about preventing the misuse of genetic information, that which makes up every one of us, our shared inheritance, and that which makes each of us unique.

This also about special interests: let us put the special interest of the health of all Americans above all else. Every one of you, and each of your loved ones, is at risk for some disease or another. We cannot yet easily reduce that risk, but it is in your hands to reduce the risk of discrimination associated with that information. At the end of the day,

we are relying on you to make it possible for individuals to use their genetic information for the health purposes for which it was elucidated. Some might say that Dr. Collins and his colleagues have done the hardest work, but we understand that balancing the policy needs of a nation is also difficult – you are pulled and pushed in many directions. . Please measure your decisions against 'what truly matters' when voting in committee and the full House floor in the next weeks. Please remember that none of us have any choice over our ancestry, our different abilities, or our genetic makeup. As a nation we do have a choice about how we treat that information.

Every American is affected by this legislation. Beyond health insurance companies', trade associations', and employers' needs, all those who carry genetic mutations they did not choose are asking us to take necessary measures to alleviate the burden discrimination — and the fear of discrimination — places on our nation. I have faith and hope that you will chose to relieve their burdens, my burden, your burden. I look forward to the good work you will do over the coming weeks. Thank you.

Biography

Sharon is President and CEO of the Genetic Alliance, a coalition of over 600 disease specific advocacy organizations working to increase capacity in advocacy organizations and to leverage the voices of the millions of individuals and families affected by genetic conditions. She is the founding Executive Director of PXE International, a research advocacy organization for the genetic condition pseudoxanthoma elasticum (PXE). Following the diagnosis of their two children with pseudoxanthoma elasticum (PXE) in 1994, Sharon, a former college chaplain, and her husband, Patrick, founded and built a dynamic organization that fosters ethical research and policies and provides support and information to members and the public.

She is at the forefront of consumer participation in genetics research, services and policy and serves as a member of many of the major governmental advisory committees on medical research, including the Food and Drug Administration Cellular, Tissue and Gene Therapies Advisory Committee and the Advisory Committee on Heritable Disorders and Genetic Diseases in Newborns and Children. She served as an Ethical Legal and Social Implications Research Advisor of NHGRI/NIH, the National Institute of Arthritis Musculoskeletal and Skin Diseases Council and currently is liaison to the National Advisory Council for Human Genome Research. She is a member of the board of directors of the Biotechnology Institute and on the advisory board of the Johns Hopkins Genetics and Public Policy Center funded by the Pew Charitable Trusts. She serves on the boards of the Coalition for 21st Century Medicine, the Personalized Medicine Coalition, DNA Direct, and the Center for Information and Study on Clinical Research Participation. She is the chair of the Coalition for Genetic Fairness, composed of advocates, healthcare providers and industry working to enact effective federal policy to prohibit genetic information discrimination. She is also chair of the Social Issues Committee of American Society of Human Genetics. In 2005, she received an honorary doctorate from Iona College for her work in community engagement and haplotype mapping.

Sharon Terry, Coalition for Genetic Fairness

Ms. Terry is a co-founder of the Genetic Alliance Biobank and serves as president of its board. It is a centralized biological and data [consent/clinical/environmental] repository catalyzing translational genomic research on rare genetic diseases. The BioBank works in partnership with academic and industrial collaborators to develop novel diagnostics and therapeutics to better understand and treat these diseases. Along with the other co-inventors of the gene associated with PXE (ABCC6), she holds the patent for the invention. She co-directs a 19-lab research consortium and manages 52 offices worldwide for PXE International.

Sharon feels strongly that advocates, working together and partnering with professionals and industry, can generate the energy and mechanisms necessary to realize the promise of biomedical research. Her work with the Genetic Alliance over the past few years has particularly focused on genetic literacy, research protections, biosample repositories, technology translation, genetic nondiscrimination, accessible services and youth issues. She has published widely on these issues. Sharon is committed to facilitating technical assistance to advocacy organizations, so that each organization benefits from the wisdom of the other. Sharon lives with Patrick and their two children in Maryland.

Testimony of Burton J. Fishman
Fortney & Scott, LLC
On behalf of the Genetic Information Nondiscrimination in Employment Coalition
Subcommittee on Health
Committee on Energy and Commerce
U.S. House of Representatives
Hearing on "H.R. 493: The Genetic Discrimination Nondiscrimination Act"
2123 Rayburn House Office Building, Washington, D.C.
March 8, 2007

Chairman Pallone, Ranking Member Deal, and distinguished members of the subcommittee. Thank you for this opportunity to testify on the issue of genetic discrimination. I commend the subcommittee for taking a role in the drafting of this far-reaching bill and the potential it creates to complicate or undermine the provision of health care, the administration of health insurance, and needlessly to intrude into the business of employers and the lives of employees. My statement will focus on the impact genetic nondiscrimination legislation will have on employers and employees.

My name is Burton Fishman. I am Of Counsel to the Washington, D.C. law firm of Fortney & Scott. By way of introduction, I served as Deputy Solicitor for National Operations at the U.S. Department of Labor under Secretary Lynn Martin, during the term of President George. H. W. Bush. I was "present at the creation" of the Americans with Disabilities Act (ADA) and have remained involved in the administration and application of that law. I have written numerous books and articles on the subject and have been involved in a number of matters with respect to the statute. That background served as a natural preface to my concerns with the issue and the bill before you today.

I appear before you this afternoon as Counsel to the Genetic Information Nondiscrimination in Employment Coalition, the GINE Coalition, which is a business Coalition of trade associations, professional organizations, individual companies and their representatives, including the Society for Human Resource Management (SHRM), the U.S. Chamber of Commerce, the National Association of Manufacturers (NAM), the National Retail Federation (NRF), and the College & University Professional Association for Human Resources (CUPA-HR), to name a few. In addition to the hundreds of thousands of members of those associations and the millions of employees they employ, representatives from biotechnology, pharmaceutical research, health care, information technology, and other industries have joined in the Coalition's deliberations. Among the Coalition's members are a number of employers who run health care facilities, provide a full-spectrum of health care services, or offer nursing, EMT, or first aid services to their employees. Their efforts to assist and treat their employees must not be impeded by this legislation.

The focus of the GINE Coalition is the issue of genetic non-discrimination in employment. However, so long as the proposed bill focuses, as it does, on the **flow** of information rather than the discriminatory misuse of information, the bill will *inevitably* be plagued by serious, negative, albeit unintended consequences. The Coalition has worked diligently and faithfully with all participants in the debate on the substance of federal legislation on the subject of genetic non-discrimination. We acknowledge and appreciate the work of the Sub-Committee on Health, Education, Labor and Pension and of the positive amendments that have made record-keeping less burdensome and have allayed fears of endless lawsuits seeking to mandate insurance coverage and/or require expanded treatment options. We nonetheless believe that the bill can be improved.

We believe that there is no need for protections of genetic information that far exceed those provided for Personal Health Information (PHI) under HIPAA or for medical information under the Americans with Disabilities Act. We believe there is no need to require that employers, who have devoted long months of effort to master the privacy rules of HIPAA, must now learn another, more expansive regimen for an ill-defined, endlessly growing body of information. We believe that **predictive** genetic information should be the focus of the bill and that this information can be acquired without inadvertently preventing the prompt provision of care or the slowing of the very research at the heart of this law. We believe that predictive genetic information can be protected without needlessly complicating the work of employers and burdening the lives of employees. In today's testimony before the Committee, I will address those issues largely in the context of Title II, as others will be focusing on Title I.

Let me be clear from the outset: **the GINE Coalition strongly supports genetic nondiscrimination and confidentiality**. The Coalition believes that employment decisions should be based on an individual's qualifications and ability to perform a job, not on characteristics that have no bearing on job performance. Although it is beyond the Coalition's brief, Coalition members' opposition to genetic discrimination in employment also extends to providing and administering health insurance to employees in a nondiscriminatory manner. Others today will speak to those insurance issues.

BACKGROUND

Members of the GINE Coalition, like the rest of society, are thrilled by and enthusiastically support the scientific research and truly spectacular breakthroughs relating to the sequencing of the human genome. Scientists in academia and industry have identified genes responsible for diseases from deafness to kidney disease to cancer. Through their efforts, we are

uncovering hereditary factors in heart disease, diabetes, Parkinson's disease, bipolar illness, asthma, and other common illnesses of our society. As Dr. Francis Collins predicted a few years ago:

> "Quite possibly before the end of the first decade of this new millennium, each of us may be able to learn our individual susceptibilities to common disorders, in some cases allowing the design of a program of effective individualized preventive medicine focused on lifestyle changes, diet and medical surveillance to keep us healthy. This will also enable us to focus our precious health care resources on maintaining wellness, instead of relying on expensive and often imperfect treatments for advanced disease.
>
> "These same discoveries about genetics will lead us to predict who will respond most effectively to a particular drug therapy, and who may suffer a side effect and ought to avoid that particular drug. Furthermore, these remarkable advances will lead us to the next generation of designer drugs, focused in a much more precise way on the molecular basis of common illnesses, giving us a much more powerful set of targeted interventions to treat disease. (Testimony of Dr. Francis Collins before the Senate Health, Education, Labor and Pension Committee, July 20, 2000)."

One comes away from such predictions with an exhilarating sense of hope and optimism for the future of medical science. Every human being has one or more defective genes, or genetic "markers," indicating a predisposition to certain abnormal traits or conditions. Given the rapid pace of genetic discoveries, in the near future, we hope, the hereditary basis for many of the profound diseases which afflict us today will not only be identified, but such knowledge will also be useful for purposes of prevention and cure. At that time, such genetic information will be

vital to an individual and his/her physician, and perhaps also to the individual's employer. The information could be used for purposes of preventing exposure to conditions in the workplace that would accelerate the onset of a particular disease or, as Dr. Collins suggested, for the purpose of fashioning individualized, employer-provided wellness programs to help prevent a disease from occurring.

However, this exhilaration is compromised by a bill, such as H.R. 493, the Genetic Information Nondiscrimination Act of 2007, which creates an amorphous definition of "genetic information" and then characterizes such information as "forbidden." We believe that penalizing the flow of information is not an appropriate response. Our concern is that the very progress in medical science that Dr. Collins envisions will be delayed and deterred by legislation such as has been proposed here. Our concern is that treatment of employee/patients will be hampered. Our concern is that employers will not be able to assist employees dealing with the various requirements of health care providers and health insurers for fear of misunderstanding the complex distinctions in the bill and being sued for their efforts.

We recognize that some people – we believe wrongly – *fear* that genetic information *may* be used by employers not for beneficent purposes but as the basis for employment discrimination. In the research community, the concern is that such fears will discourage individuals from participating in genetic research and testing. Such fears are fed by anecdotal but apocryphal stories and, of course, on the rare but highly publicized case involving Burlington Northern-Santa Fe Railroad, from nearly a decade ago.[1] The fact that the employees in this case were able to seek and gain redress under current law indicates that no additional legislation is

1 *EEOC v. Burlington Northern Santa Fe Railroad* (N.D Ia, settled April 18, 2001).

required. As significant, what occurred there was an *unusual and unrepeated* event, one that should not serve as the basis for sweeping legislation.

Indeed, there are surveys conducted by neutral bodies such as the American Management Association which show that few employers seek or even understand genetic information. Further, in the more than 30 states which have laws prohibiting genetic discrimination, there have been ***no*** reported cases, even though several statutes were enacted decades ago. Thus, there is no empirical evidence of genetic discrimination in employment, unlike the mountains of evidence of discriminatory conduct which preceded passage of other nondiscrimination laws, such as Title VII of the 1964 Civil Rights Act, the Age Discrimination in Employment Act, and the Americans with Disabilities Act.

Somewhere in the distracting mix of irrational fears, a rational understanding of the benefits of genetic research has been lost. Somewhere, the important assistive role that employers, hospitals, and insurers play in transmitting and explaining often complicated rules and regulations has been forgotten. Somewhere, the legitimate concern for worker safety by government and by employers has been overlooked and replaced with notions of the sanctity of the genome. But the product of genetic research is not employment discrimination. The product of genetic research will be to help people – employees and employers – make health-driven choices based on shared knowledge. But viewed through the distorting prism of H.R. 493, the response to advances in genetic research is to prohibit the spread of information. H.R. 493 responds to fear and ignores hope. It limits the spread of information in the name of worker fear rather than finding ways of applying that information in the name of worker safety. That is not how Congress has responded in the past and should not be how Congress responds today. Fear should not be the predicate for federal legislation.

This is particularly true in the still-nascent field of genetic testing. Currently, the predictive ability of genetic tests and other forms of genetic information has little practical workplace utility since, in the current state of medical and scientific diagnostics, genetic tests reveal only the possibility that a particular trait, condition, or illness may develop in the future. There is no medical certainty that such illnesses will, in fact, ever develop; neither is there any certainty as to how far in the future they may become manifest. Thus, such information is simply too remote and too speculative on which to base current employment decisions, even if an employer were interested in doing so – a conclusion utterly unsupported by actual conduct. Furthermore, because of the awe-inspiring speed at which scientific knowledge is expanding, legislation based on today's understanding will likely respond to a scientific context that has already fallen into obsolescence. In fact, many of the states which passed legislation early on, have already had to amend laws rendered obsolete by the advance of scientific knowledge.

Yet, it is the opinion of the sponsors and supporters of pending federal genetic nondiscrimination bills that such legislation is necessary. Although we do not share that view, as a Coalition that stands squarely against employment discrimination, we do not oppose legislation that focuses on the discriminatory misuse of genetic information. To achieve that goal, we believe the proposed bill should continue to be amended and improved. We hope to work with Congress to craft an effective, efficiently administered, practical law that avoids unintended consequences and baseless lawsuits, and which will not impede progress in science.

THE GINE COALITION'S POSITION ON GENETIC NONDISCRIMINATION

The GINE Coalition has developed a set of core principles by which it measures genetic nondiscrimination legislation. The Genetic Information Non-Discrimination in Employment (GINE) Coalition endorses the following legislative principles:

- The members of the Coalition believe that employment decisions should be made based on an individual's qualifications and ability to perform a job, not on the basis of characteristics that have no bearing on job performance. Therefore, we strongly oppose employment discrimination on the basis of a person's predictive genetic information.
- Possession of genetic information must be differentiated from the use of this information for discriminatory purposes. Any proposed statute should be directed at controlling discriminatory conduct, rather than attempting to regulate the flow of information. As we like to say, genetic discrimination is about discrimination, not genetics.
- We believe that genetic discrimination is wrong, and if a company intentionally discriminates, remedies should be available. However, the Coalition opposes legislation that would provide excessive punitive and compensatory damages or that would expose employers to baseless litigation. Furthermore, no employer should be at risk of liability for innocently receiving information that is deemed "genetic" or disclosing such information for the purposes permitted by HIPAA for Personal Health Information (PHI). Nor should employers face punitive damages for technical or recordkeeping violations.
- Duplicative efforts to guard against genetic discrimination are costly and confusing. Any legislative proposals regarding genetic discrimination should take into account the protections already offered by the HIPAA and its regulations, the ADA, and other federal, state, and local statutes and regulations.

In sum, the GINE Coalition's Statement of Principles embraces the letter and spirit of nondiscrimination and espouses the idea that discrimination, not information, should be the target of any such legislation. These principles are explained in more detail as follows.

Let me state again, the GINE Coalition supports the policy of nondiscrimination in employment based on an individual's genetic makeup or pre-disposition to certain diseases or conditions. Employment decisions should be based on an individual's qualifications and ability to perform a job, not on the basis of other characteristics or imputed attributes that have no bearing on job performance.

Further, being mindful of the rapid developments in genetic research and Dr. Collin's predictions regarding the beneficial use of genetic information in the near future, we believe that genetic non-discrimination legislation must be carefully and narrowly drafted. "Genetic information" should be precisely defined to include only **predictive** genetic information regarding inherited alterations in genetic material or genes which are associated with a disease or illness that is asymptomatic at the time of testing. ***Possession*** of genetic information must be differentiated from the ***use*** of such information for discriminatory purposes. Legislation should be directed at controlling and punishing discriminatory conduct, rather than regulating and burdening the flow of information. The law should not trigger liability based on an employer's mere receipt of genetic information, such as through conversations concerning a relative's illness or derived from such normative behavior as visiting the sick and consoling the bereaved.

Thus, our hope today is to sound a note of caution and urge this Committee to carefully consider the impact of its actions. In light of the absence of any evidence of the use of genetic information for discriminatory purposes, there is no urgent need to act speedily.

As Congress has the time to act with deliberation and care to draft a law, we urge the subcommittee to ensure that any genetic discrimination legislation:

1. Defines "genetic information" narrowly to include only predictive genetic information regarding inherited alterations in genetic material or genes which are associated with a disease or illness that is asymptomatic at the time of testing;
2. Adopts the protections and permits the acquisition, use, and disclosure of genetic information for the same purposes as permitted for Personal Health Information under HIPAA;
3. Resolves conflicts among Federal laws and between Federal and state standards with respect to employment discrimination and the administration of employee welfare benefit plans;
4. Creates a single Federal standard;
5. Permits the request and receipt of genetic information not only under the FMLA, but also under the ADA, HIPAA, and other more likely sources of such information; and
6. Protects employers from punitive damages for technical violations.

Definition of "Genetic Information"

In January, 2007, Rep. Slaughter, a principal sponsor of H.R. 493, testified to her understanding of this bill's purpose. She stated that "GINA prohibits group health plans and health insurers from denying coverage to a healthy individual or charging that person higher premiums based **solely on a genetic predisposition to develop a disease in the future**." (emphasis added). We believe this bill should reflect that purpose. The definition of "genetic information" as currently stated in H.R. 493 dispenses with a focus on predictive genetic information related to an inheritable but currently asymptomatic disease. In its place is a

definition that is so broad as to include "the occurrence of a disease or disorder in family members of the individual" (Sec. 201 (4)(A)(iii)), without **any** limitation. We do not believe that Congress intended colds and the flu, upset stomachs and chicken pox to be part of this bill. The definition of "genetic information" should be limited to **predictive** genetic information regarding inherited alterations in genetic material or genes which are associated with a disease or illness that is asymptomatic at the time of testing.

Protections and Exceptions of HIPAA

As currently drafted, H.R. 493 creates a protective program for "genetic information" that far exceeds that for PHI under HIPAA. We do not understand why information relating to a distant, contingent eventuality requires protections different from and greater than those for existing medical problems. We do not understand why a separate protective program needs to be invented and mastered **after** employers have labored so long to understand and put the highly reticulated HIPAA program into place.

Further, the protective program of H.R. 493, as articulated in Sections 206 and 210, does not promote patient care or sound public policy. There is no general exception for disclosures for treatment; there is no exception for disclosures to treating physicians, to unfolding police investigations, to government officials investigating something other than compliance with *this* law, and so on. Because Section 210 permits only the disclosure of "medical informant that is not genetic information," for example, a company nurse could **not** advise an EMT or physician that the trauma patient she is treating ***for a manifested condition*** just disclosed that his father also had heart trouble. That cannot be your intent.

Under the HIPAA privacy regulations, disclosures of PHI are allowed for a variety of purposes including for treatment, for civil and criminal litigation (including disclosures to litigation counsel) under clearly stated, limited circumstances, to government public health officials, for law enforcement, to identify a victim of a crime or to apprehend a criminal, and more. These disclosures were permitted after a lengthy regulatory process including considerable pubic comment. The fruits of that process should be respected here and the exceptions in the HIPPA privacy scheme should be incorporated here. (A chart presenting the differences in the protective schemes of H.R. 493 and that of HIPAA is attached to this testimony.)

Indeed, this bill should clearly state that it does not create any new restrictions or requirements with respect to the actions or communications regarding the delivery of health care including any health services, pharmacies, health records services, health counseling, or health education even if provided for or sponsored by an employer for employees.

Conflict among Federal Laws and Between Federal and State Standards

Should a new federal genetic discrimination law be enacted, the Coalition believes it is essential that it be made to precisely mirror the requirements and protections of existing employment statutes and that it not conflict with current laws or disrupt existing nondiscriminatory employment practices.

As a practical consideration, there is always concern that new employment legislation will be drafted without due consideration being given to its impact on and its interaction with existing laws. The interrelationship and interaction among the ADA, FMLA and state workers' compensation law, all of which impose different legal requirements, demonstrates this problem.

Because each law was passed at a different time and has a different policy objective, an employer's efforts to comply with one law can easily cause it to be in conflict with provisions of the other laws. Employment laws are most effective when compliance with one federal or state law does not contradict other laws or does not require employers to violate one law to satisfy another.

Any genetic nondiscrimination legislation must be balanced, objective, and developed with existing law in mind. Any legislative proposals regarding genetic discrimination should take into account and be in accordance with the protections already offered by the HIPAA and its regulations, the ADA, and other federal, state, and local statutes and regulations. Duplicative efforts to guard against genetic discrimination are costly, confusing, and unnecessary.

Lack of a Single Federal Standard

H.R. 493 would not create a single federal standard, but unfortunately would allow a patchwork of state standards to impose inconsistent requirements. Any Federal legislation should recognize the problems faced by employers as they try to comply with the numerous genetic discrimination laws already in existence. More than 30 states have enacted laws prohibiting discrimination based on genetic information. However, these laws vary widely. If Congress enacts legislation barring employment discrimination based on genetic information then it should include a safe harbor providing that employers in compliance with the federal standards cannot be liable under state or local laws banning such discrimination. There should be only one standard, *your* standard.

Permitting Receipt of Genetic Information

Under the proposed bill, genetic information may lawfully be acquired from *some* sources, such as FMLA medical certifications and workers' compensation forms, whereas the same information from more likely sources, such as employer-provided sick or family leave that is not FMLA qualifying, ADA accommodations or discussions regarding health insurance coverage under HIPAA or COBRA, is not allowed.

The interplay of the proposed legislation and the ADA and HIPAA creates significant difficulties. Employer efforts to make timely and accurate determinations regarding requests for accommodations or claims brought under current law should not be inhibited or made illicit.

Finally, many employers provide leave for illnesses not covered by the FMLA, or beyond what is mandated by the FMLA for medical and family reasons or provide similar leave but fall below the 50 employee threshold under the FMLA. In order to administer these leave programs, employers routinely require employees to provide documentation of the need for leave. Exposing employers to liabilities for requiring documentation will discourage them from offering these leave benefits.

It is imperative that legislative efforts be focused on prohibiting the discriminatory use of genetic information, not on the flow of such information. There should be a broad exception permitting the acquisition of all such information, if collected pursuant to law and retained in confidential files. The information should not be the issue; the misuse of the information should.

Punitive Damages for Technical Violations

All parties share the goal of eliminating discrimination in the workplace, from the hiring process to providing benefits. When a company intentionally discriminates, remedies should be available. However, the Coalition opposes legislation that that would expose employers to baseless litigation and would provide punitive and compensatory damages *absent* actual discrimination. To assist an employee in receiving health insurance coverage or benefits should never give rise to a cause of action. Relating pertinent family history to an Emergency Medical Technician or other health care provider should never be the basis of a lawsuit. Given the availability of significant protections under other laws, administrative enforcement and equitably based remedies (including loss of wages and benefits) should be sufficient to allay fear of possible discrimination while mitigating the risk of a dramatic increase in baseless and inherently expensive litigation. Unfortunately, the House bill resorts to jury trials with punitive and compensatory damages for *any* violation, without distinction, which will necessarily invite additional litigation.

The balance of our submission is a discussion of existing state and federal laws which have a bearing on genetic discrimination in the workplace, and specific concerns with pending federal legislation. We believe they support the Coalition's belief that the current absence of claims of genetic discrimination in employment grows that the fact that (1) employers have no interest in acquiring such data and (2) current laws already prohibit and punish such conduct. That, in turn, supports the Coalition's belief that Congress faces no urgent need to act and can duly deliberate the implications of this or any legislation regarding genetic discrimination in the workplace.

CURRENT LAWS RELATING TO GENETIC NONDISCRIMINATION

A. State Laws

State legislatures have been the pioneers in enacting laws governing various aspects of genetic information in the workplace. To date, laws enacted in over 30 states address (in one form or another) the issue of genetic discrimination in employment. In addition, other state laws may address additional select aspects of genetic information.

The state experience is valuable for a number of reasons—not least of these is that it shows the 'cost' of hasty legislation in a rapidly developing area. No fewer than six states have already had to revise their laws to keep pace with scientific advances. More than any other feature of state law, this promises to be model for federal legislation.

The 1948 McCarran-Ferguson Act explicitly grants insurance regulation to the states. The Employee Retirement Income Security Act of 1974 ("ERISA") preempts state laws pertaining to self-funded employee benefits plans. In 1996, the Health Insurance Portability and Accountability Act ("HIPPA") became the first federal law to directly address genetic information. The law prohibits health insurance discrimination based on any "health status-related factor," including genetic information, for group health plans. Laws governing genetic discrimination in 34 states have complemented HIPPA protections related to health insurance.

B. Executive Order 13145

On February 8, 2000, President Clinton signed Executive Order 13145, which prohibits discrimination in federal employment on the basis of genetic information. The EEOC was assigned responsibility for the Executive Order and its enforcement under the Americans with Disabilities Act. On July 26, 2000, the EEOC issued a Policy Guidance explaining the

definitions, Prohibitions, and exceptions in Executive Order 13145.

C. Title VII of the Civil Rights Act of 1964

Title VII of the 1964 Civil Rights Act may provide some protection against genetic discrimination where such discrimination may have "disparate impact" based on race, sex, religion or national origin, e.g., sickle cell anemia (African-Americans), Tay Sachs (Ashkenazi Jews).

D. Genetic Information and the Americans with Disabilities Act

State and federal statutes prohibiting disability discrimination in employment are the most likely source of genetic information protections. The ADA protects individuals with one or more physical or mental impairments that substantially limits the individual in performing a major life activity; an individual with a record of such impairment; or an individual who is "regarded as" having such an impairment. It is clear that the ADA covers individuals who have a genetically-related disability once it is manifest and substantially limits a major life activity. Also, the ADA covers individuals with a prior record of a genetically-related disability that is manifest. However, the courts have not yet determined definitively whether the ADA should be construed to cover employment discrimination on the basis of genetic information concerning diagnosed, but asymptomatic, genetic conditions which are not manifest. To this point, virtually no case law exists regarding ADA coverage of genetic discrimination in the workplace.

That being said, the EEOC has long taken the position that the Americans with Disabilities Act protects individuals with asymptomatic genetic conditions from discrimination in employment. The EEOC successfully filed against Burlington Northern-Santa Fe Railroad based on genetic testing of employees for a genetic marker related to carpal tunnel syndrome.

The notoriety of that incident demonstrates that it was a unique event. It also demonstrates that current laws were able to resolve the matter completely. After swift government enforcement actions, the parties reached a settlement on the EEOC suit in April 2001, in which the railroad agreed to stop testing. As was stated before the House on July 24, 2001 by one of those improperly tested by Burlington-Northern, the EEOC's actions were exceptional, effective, and exemplary.

Given the EEOC's guidance on this issue, as well as their enforcement history, employers should expect EEOC enforcement actions and individual charges under the "regarded as" prong of the ADA, if they choose to make employment decisions involving individuals with genetic disorders based upon myths, fears, or stereotypes, rather upon the person's ability to perform specific required job tasks, with or without reasonable accommodation, in a safe manner.[2]

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[2]We should recognize, however, that there may be perfectly valid and non-discriminatory reasons for an employer to consider an employee's genetic information in order to ensure that the employee is working in an environment that would not exacerbate the employee's genetic predisposition to an illness or other health condition. The ADA recognizes that an employer may impose the qualification standard that an employee not poses a "direct threat" to the health or safety of others in the workplace. 42 U.S.C. Sec. 12113(b). The EEOC has expanded this statutory definition to include the individual with a disability. 29 C.F.R. Sec. 1630.2(r). Protection of a worker may mean that for his or her health and the safety of others, the individual should not be assigned to a job. In *Echazabal v. Chevron*, 536 U.S. 73 (2002), the Supreme Court unanimously ruled that the EEOC's interpretation was correct and that an employer may legitimately object to idly permitting an employee's self-inflicted exposure to injury or worse.

LIMITATIONS ON GENETIC TESTING IN THE WORKPLACE

An employer's ability to engage in genetic testing and to use the results of such testing in making a variety of employment decisions may already be limited in a number of ways by the provisions of the Americans with Disabilities Act. 42 U.S.C. Sec. 12101, *et seq.* Genetic testing is a medical examination and the ADA contains specific provisions limiting the manner in which an employer may conduct medical examinations and inquiries.

The ADA contains specific provisions dealing with the ability of an employer to request or obtain medical information or to require medical examinations. The ADA prohibits absolutely any medical inquiries or medical examinations at the pre-offer stage of the employment application process. 42 U.S.C. Sec. 12112(d)(2)(A). Genetic screening clearly constitutes a medical inquiry or examination and, hence, the ADA would prohibit an employer, for example, from requiring all job applicants to undergo genetic screening.

Once an offer of employment has been made, the employer may condition Sec. that offer upon the successful completion of a medical examination. *Id.* at Sec. 12112(d)(3). This so-called conditional offer medical examination specifically is authorized under the ADA and the statute contains no limitations upon the scope of such an examination. Hence, the ADA, at this stage of the employment process, would not prohibit or limit the ability of an employer to engage in genetic screening. To give a conditional offer examination, however, an employer must satisfy three requirements. First, the examination must be given to all entering employees regardless of disability. *Id.* at Sec. 12112(d)(3)(A). Second, the information obtained must be collected and maintained in a confidential manner. 42 U.S.C. Sec. 12112(d)(3)(B).[3] Third, the

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[3] The ADA authorizes disclosure of medical information obtained from a conditional medical examination only in the following circumstances:

statute requires that the results of any medical examination may be used only in accordance with the non-discrimination requirements of the statute. *Id.* Sec. 12112(d)(3)(C). Generally, this requirement means that an employer may revoke a conditional offer of employment only if the results of the medical examination demonstrate that the individual cannot perform the essential functions of the job with or without reasonable accommodation.

Finally, the ADA limits an employer's ability to conduct medical examinations or make medical inquiries of current employees to those circumstances where the examination or inquiry can be shown to be "job related and consistent with business necessity." 42 U.S.C. Sec. 12112(b)(4)(A). This standard has been interpreted by the EEOC as relating to an employee's present ability to perform the job. *See* 29 C.F.R. App. Sec. 1630.10 (there should be "a fit between job criteria and an applicant's (or employee's) actual ability to do the job."). Because genetic testing normally addresses what may occur in the future, not an individual's actual ability to perform specific job tasks, in most cases, it is unlikely the ADA would allow genetic testing of current employees under the "job relatedness" standard.[4]

The current trend of judicial decisions recognizes that non-disabled individuals may enforce the statute's restrictions on medical inquiries.[5] Hence, even if an individual with a genetic marker or defect is not deemed to be "disabled" within the definition of the ADA, the

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- To supervisors and managers who need to be informed about necessary restrictions on the work duties of the employee and any necessary accommodation;
- To first aid and safety personnel; and
- To government officials investigating compliance with the ADA.

42 U.S.C. Sec. 12112(d)(3)(B)(i)-(iii).

[4]An exception may arise where federal regulations, such as those promulgated by OSHA, would require an employer to engage in medical monitoring of employees. *See, e.g.,* 29 U.S.C. ' 655(c)(7) (providing for the monitoring of employee exposure for employee safety).

[5]See *Cossette v. Minnesota Power & Light Co.,* 188 F.3d 964 (8th Cir. 1999); *Griffin v. Steel Tech, Inc.,* 160 F.3d 591, 594 (10th Cir. 1998); *Fredenburg v. Contra Costa County Dept. of Health Services,* 172 F.3d 1176, 1182 (9th Cir. 1999).

statue still protects the person from being required to undergo genetic testing unless the testing complies with the above requirements.

CONCLUSION

In closing, the Genetic Information Nondiscrimination in Employment Coalition believes that genetic discrimination is wrong. To reiterate, we believe that employment decisions should be based on an individual's qualifications and ability to perform a job, not on the basis of characteristics that have no bearing on job performance.

The GINE Coalition believes that any federal legislation prohibiting genetic discrimination in employment should focus on controlling discriminatory conduct, not the flow of information, should conform to other federal employment discrimination laws, should create a single federal standard, should avoid duplicative administrative burdens, and should not impede the beneficent results of the remarkable research now taking place. Finally, such legislation should not be so broadly constructed as to encourage frivolous litigation. By acknowledging the principles set forth in this testimony, the subcommittee can help make this legislation more effective.

Again, I thank the subcommittee for listening to our perspective on the issue of genetic discrimination and for its invitation to testify today. The Coalition looks forward to working with you – in the future, as in the past – to make this the best possible law. I will be happy to answer any questions you may have.

COMPARISON OF H.R. 493 and HIPAA PRIVACY PROGRAMS

H.R. 493	HIPAA
Permitted Uses and Disclosures	
(1) to the employee (or family member if the family member is receiving the genetic services) or member of a labor organization at the request of the employee or member of such organization;	**(1) To the Individual.** A covered entity may disclose protected health information to the individual who is the subject of the information.
	(2) Business Associates [*45 CFR 164.502(e), 164.504(e),164.532(d) and (e)*] The Privacy Rule allows covered providers and health plans to disclose protected health information to these "business associates" if the providers or plans obtain satisfactory assurances that the business associate will use the information only for the purposes for which it was engaged by the covered entity, will safeguard the information from misuse, and will help the covered entity comply with some of the covered entity's duties under the Privacy Rule. Covered entities may disclose protected health information to an entity in its role as a business associate *only* to help the covered entity carry out its health care functions – not for the business associate's independent use or purposes, except as needed for the proper management and administration of the business associate.
	(3) Treatment, Payment, Health Care Operations. A covered entity may use and disclose protected health information for its own treatment, payment, and health care operations activities. A covered entity also may disclose protected health information for the treatment activities of any health care provider, the payment activities of another covered entity and of any health care provider, or the health care operations of another covered entity involving either quality or competency assurance activities or fraud and abuse detection and compliance activities, if both covered entities have or had a relationship with the individual and the protected health information pertains to the relationship.

	Treatment is the provision, coordination, or management of health care and related services for an individual by one or more health care providers, including consultation between providers regarding a patient and referral of a patient by one provider to another. ***Payment*** encompasses activities of a health plan to obtain premiums, determine or fulfill responsibilities for coverage and provision of benefits, and furnish or obtain reimbursement for health care delivered to an individual[1] and activities of a health care provider to obtain payment or be reimbursed for the provision of health care to an individual. ***Health care operations*** are any of the following activities: (a) quality assessment and improvement activities, including case management and care coordination; (b) competency assurance activities, including provider or health plan performance evaluation, credentialing, and accreditation; (c) conducting or arranging for medical reviews, audits, or legal services, including fraud and abuse detection and compliance programs; (d) specified insurance functions, such as underwriting, risk rating, and reinsuring risk; (e) business planning, development, management, and administration; and (f) business management and general administrative activities of the entity, including but not limited to: de-identifying protected health information, creating a limited data set, and certain fundraising for the benefit of the covered entity. Most uses and disclosures of psychotherapy notes for treatment, payment, and health care operations

	purposes require an authorization as described below. Obtaining "consent" (written permission from individuals to use and disclose their protected health information for treatment, payment, and health care operations) is optional under the Privacy Rule for all covered entities.[ii] The content of a consent form, and the process for obtaining consent, are at the discretion of the covered entity electing to seek consent.
	(4) Uses and Disclosures with Opportunity to Agree or Object. Informal permission may be obtained by asking the individual outright, or by circumstances that clearly give the individual the opportunity to agree, acquiesce, or object. Where the individual is incapacitated, in an emergency situation, or not available, covered entities generally may make such uses and disclosures, if in the exercise of their professional judgment, the use or disclosure is determined to be in the best interests of the individual. ***Facility Directories.*** It is a common practice in many health care facilities, such as hospitals, to maintain a directory of patient contact information. A covered health care provider may rely on an individual's informal permission to list in its facility directory the individual's name, general condition, religious affiliation, and location in the provider's facility.[iii] The provider may then disclose the individual's condition and location in the facility to anyone asking for the individual by name, and also may disclose religious affiliation to clergy. Members of the clergy are not required to ask for the individual by name when inquiring about patient religious affiliation. ***For Notification and Other Purposes.*** A covered entity also may rely on an

	individual's informal permission to disclose to the individual's family, relatives, or friends, or to other persons whom the individual identifies, protected health information directly relevant to that person's involvement in the individual's care or payment for care. This provision, for example, allows a pharmacist to dispense filled prescriptions to a person acting on behalf of the patient. Similarly, a covered entity may rely on an individual's informal permission to use or disclose protected health information for the purpose of notifying (including identifying or locating) family members, personal representatives, or others responsible for the individual's care of the individual's location, general condition, or death. In addition, protected health information may be disclosed for notification purposes to public or private entities authorized by law or charter to assist in disaster relief efforts.
	(5) Incidental Use and Disclosure. The Privacy Rule does not require that every risk of an incidental use or disclosure of protected health information be eliminated. A use or disclosure of this information that occurs as a result of, or as "incident to," an otherwise permitted use or disclosure is permitted as long as the covered entity has adopted reasonable safeguards as required by the Privacy Rule, and the information being shared was limited to the "minimum necessary," as required by the Privacy Rule.
(2) to an occupational or other health researcher if the research is conducted in compliance with the regulations and protections provided for under part 46 of title 45, Code of Federal Regulations;	**(6) Research.** "Research" is any systematic investigation designed to develop or contribute to generalizable knowledge.[iv] The Privacy Rule permits a covered entity to use and disclose protected health information for research purposes, without an individual's authorization, provided the covered entity obtains either: (1) documentation that an alteration or waiver of individuals' authorization for the use or disclosure of protected health information about them for research purposes has been approved by an Institutional Review Board or Privacy

	Board; (2) representations from the researcher that the use or disclosure of the protected health information is solely to prepare a research protocol or for similar purpose preparatory to research, that the researcher will not remove any protected health information from the covered entity, and that protected health information for which access is sought is necessary for the research; or (3) representations from the researcher that the use or disclosure sought is solely for research on the protected health information of decedents, that the protected health information sought is necessary for the research, and, at the request of the covered entity, documentation of the death of the individuals about whom information is sought. A covered entity also may use or disclose, without an individuals' authorization, a limited data set of protected health information for research purposes (see discussion below).
(3) in response to an order of a court, except that-- (A) the employer, employment agency, labor organization, or joint labor-management committee may disclose only the genetic information expressly authorized by such order; and (B) if the court order was secured without the knowledge of the employee or member to whom the information refers, the employer, employment agency, labor organization, or joint labor-management committee shall provide the employee or member with adequate notice to challenge the court order;	**(7) Required by Law.** Covered entities may use and disclose protected health information without individual authorization as *required by law* (including by statute, regulation, or court orders).
	(8) Public Health Activities. Covered entities may disclose protected health information to: (1) public health authorities authorized by law to collect or receive such information for preventing or controlling disease, injury, or disability and to public health or other government authorities authorized to receive reports of child abuse and neglect; (2) entities subject to FDA regulation regarding FDA regulated

	products or activities for purposes such as adverse event reporting, tracking of products, product recalls, and post-marketing surveillance; (3) individuals who may have contracted or been exposed to a communicable disease when notification is authorized by law; and (4) employers, regarding employees, when requested by employers, for information concerning a work-related illness or injury or workplace related medical surveillance, because such information is needed by the employer to comply with the Occupational Safety and Health Administration (OHSA), the Mine Safety and Health Administration (MHSA), or similar state law.
	(9) Victims of Abuse, Neglect or Domestic Violence. In certain circumstances, covered entities may disclose protected health information to appropriate government authorities regarding victims of abuse, neglect, or domestic violence.
	(10) Health Oversight Activities. Covered entities may disclose protected health information to health oversight agencies (as defined in the Rule) for purposes of legally authorized health oversight activities, such as audits and investigations necessary for oversight of the health care system and government benefit programs.
	(11) Judicial and Administrative Proceedings. Covered entities may disclose protected health information in a judicial or administrative proceeding if the request for the information is through an order from a court or administrative tribunal. Such information may also be disclosed in response to a subpoena or other lawful process if certain assurances regarding notice to the individual or a protective order are provided.
(4) to government officials who are investigating compliance with this title if the information is relevant to the investigation; or	**(12) Law Enforcement Purposes.** Covered entities may disclose protected health information to law enforcement officials for law enforcement purposes under the following six circumstances, and

	subject to specified conditions: (1) as required by law (including court orders, court-ordered warrants, subpoenas) and administrative requests; (2) to identify or locate a suspect, fugitive, material witness, or missing person; (3) in response to a law enforcement official's request for information about a victim or suspected victim of a crime; (4) to alert law enforcement of a person's death, if the covered entity suspects that criminal activity caused the death; (5) when a covered entity believes that protected health information is evidence of a crime that occurred on its premises; and (6) by a covered health care provider in a medical emergency not occurring on its premises, when necessary to inform law enforcement about the commission and nature of a crime, the location of the crime or crime victims, and the perpetrator of the crime.
	(13) Decedents. Covered entities may disclose protected health information to funeral directors as needed, and to coroners or medical examiners to identify a deceased person, determine the cause of death, and perform other functions authorized by law.
	(14) Cadaveric Organ, Eye, or Tissue Donation. Covered entities may use or disclose protected health information to facilitate the donation and transplantation of cadaveric organs, eyes, and tissue.
	(15) Serious Threat to Health or Safety. Covered entities may disclose protected health information that they believe is necessary to prevent or lessen a serious and imminent threat to a person or the public, when such disclosure is made to someone they believe can prevent or lessen the threat (including the target of the threat). Covered entities may also disclose to law enforcement if the information is needed to identify or apprehend an escapee or violent criminal.
	(16) Essential Government Functions. An authorization is not required to use or disclose protected health information for certain essential government functions.

	Such functions include: assuring proper execution of a military mission, conducting intelligence and national security activities that are authorized by law, providing protective services to the President, making medical suitability determinations for U.S. State Department employees, protecting the health and safety of inmates or employees in a correctional institution, and determining eligibility for or conducting enrollment in certain government benefit programs.
	(17) Workers' Compensation. Covered entities may disclose protected health information as authorized by, and to comply with, workers' compensation laws and other similar programs providing benefits for work-related injuries or illnesses.
	(18) Limited Data Set. A limited data set is protected health information from which certain specified direct identifiers of individuals and their relatives, household members, and employers have been removed. A limited data set may be used and disclosed for research, health care operations, and public health purposes, provided the recipient enters into a data use agreement promising specified safeguards for the protected health information within the limited data set.
(5) to the extent that such disclosure is made in connection with the employee's compliance with the certification provisions of section 103 of the Family and Medical Leave Act of 1993 (29 U.S.C. 2613) or such requirements under State family and medical leave laws.	**N/A**

Statement of Frank S. Swain before the Subcommittee on Health
Committee on Energy and Commerce
US House of Representatives
regarding the Genetic Information Nondiscrimination Act of 2007
March 8, 2008

Chairman Pallone, Representative Deal and Members of the Subcommittee:

Thank you for inviting my testimony at this hearing. There is no issue I have worked on, in my nearly 30 year professional career in legal and public policy issues in Washington, that is more important to as many people over the long and short term than this legislative proposal.

Purpose of the bill

The purpose of the legislation is quite simple. This bill will assure that highly personal genetic information, as intrinsic to the individual as skin color, and so much more significant, is not the basis for employment or insurance discrimination. It will encourage the individual to pursue any and all genetic testing and analysis which is medically prudent, untroubled by apprehension over the possibility of misuse of the information in non-medical contexts.

It is an accepted value of our society and guaranteed by law that persons may not be subject to discrimination in the workplace or insurance markets because of race or national origin. Our skin color or our parents' ethnicity are factors over which we have no control and which do not determine our ability to work hard and have a successful life. It is, however, perfectly appropriate for insurers or employers to make decisions based on our behavioral choices, whether we choose to work hard, whether we elect to smoke, skydive or pursue other risky practices.

Likewise, we are born with our 46 chromosomes and 30,000 genes. We cannot control or change them. And although we have known for 50 years that these genes were made up of a helical DNA code, we did not know what that code looked like and what it meant. Now, 50 years later, thanks to the splendid work of Dr. Collins and his colleagues, and substantial support from the US Congress and taxpayers, that human genetic code is sequenced, illustrated, mapped, for anyone to see and analyze. This era could not be more exciting at a health and disease research level or more worrying at a personal level.

Researchers now know what the genome looks like, and are plunging ahead to determine what the genes do. Reports in the research and medical literature appear daily of potential discoveries of genes associated with various health conditions. With this knowledge comes opportunity for development of cures or more efficacious treatments, perhaps personalized to the individual. But with knowledge, particularly the partial knowledge of some of this early research, comes confusion, apprehension and concern, especially for the person whose genes are being analyzed.

Context of the bill

Of the more than 1,000 genetic tests presently available, most are offered for purposes of either diagnosis of a particular current health condition, or analysis of whether a particular drug or course of treatment for a health condition will be efficacious or dangerous. Use of such manifest disease related tests is not affected by this bill. Insurance companies would be free to make

decisions on coverage and administration of payment for such tests, and analyze the utility of such tests at the individual or large group level. This bill would not affect the employer's handling of such tests, as that is already largely governed by the Americans with Disabilities Act (ADA). Once a disease is manifest, that condition cannot trigger discrimination under the ADA.

However, there are some genetic tests which merely inform whether an individual may, in the future, manifest a certain health condition. Such tests are not likely to predict exactly when the individual may show disease symptoms, the course of the disease, or how severe the particular individual's condition may be. For all but a few health conditions, it will not even dispositively predict that the individual will acquire the condition. Employer or insurer use of such individual genetic information, which may predict future disease, is not today prohibited by Federal law. It is this "gap" which the Genetic Information Nondiscrimination Act fills.

Certainty and Predictability

Individuals want to know that their own genetic maps will not be misused. Employers and insurers need reasonable and unburdensome ground rules for managing and properly using such information. This bill accomplishes both goals.

I come to this issue having served as legislative counsel to the National Federation of Independent Business for four years and having been nominated by and served President Reagan for eight years as Chief Advocate at the Small Business Administration. The concerns of small business and the small employer must always be taken seriously in any policy debate. This bill takes a responsible and modest approach.

First, most employers will not be affected at all. Genetic information is not today typically collected or acquired by employers. But with the information becoming more common, less expensive to obtain, and more easily transmittable through electronic records, the time to establish ground rules is now, before problems become widespread.

Second, the employment provisions are established within an existing body of law, whose processes, procedures and enforcement mechanisms have been well defined through decades of Congressional adjustment and administrative and judicial precedent. This bill does not depend on executive rulemaking or definitions of foggy concepts in order to become effective and predictable.

Third, employers and insurers who inadvertently acquire such information are not penalized. Thanks to an amendment adopted by the Education and Labor Committee, it should be clear that employers do not need to establish separate record keeping systems. The bill is targeted at the improper use of predictive genetic information, not the mere possession of it in whatever kind of file.

Summary

In the long run, the Genetic Information Nondiscrimination Act will be one of the most important accomplishments of this or any Congress. It will protect the individual, stimulate research, encourage treatment advances, at nearly no cost to the government or the private sector. This bill has strong bipartisan support and has been carefully reviewed and improved, reflecting many parties' input. I encourage this Committee to report the bill.

Summary of Testimony
Kathy Hudson, Ph.D.
Director, Genetics and Public Policy Center
March 8, 2007

- The American public is very enthusiastic about the promise of genetic medicine and supports the use of genetic testing in healthcare to learn about future risk of disease. The public also is very supportive of genetic research.
- A survey completed this week by the Genetics and Public Policy Center of 1,199 Americans shows a large majority trusts doctors and genetic researchers and supports genetic testing in health care and research.
- Growing uncertainty and fear threaten the future of genetic medicine. Today, more than 90 percent of Americans are concerned that results from a genetic test that can tell patients whether they are at increased risk for a disease like cancer could be used in ways that would be harmful to them; nearly half of all Americans say they are *very* concerned.
- Nearly all Americans (93 percent) believe that health insurers should not be able to use a person's genetic test results about increased risk of future disease to deny or limit insurance or charge higher prices. Similarly, 93 percent feel that employers should not be able to use this type of genetic test result to make decisions about hiring and promotion.
- More than three-quarters of Americans believe there should be a law that prevents employers from using genetic test results about risk of future disease to make decisions about hiring and promotion; three-quarters also believe there should be a law to prevent health insurers from using genetic test results about risk of future disease to deny or limit insurance or charge higher prices.
- HR 493 goes a long way toward filling the gaps in current law and calming a wary public by making clear that genetic information that is revealed through testing cannot be used to deny insurance to or otherwise prevent an unaffected individual from obtaining the insurance they need. Nor can an employer use such information to discriminate on the job.
- HR 493 prevents the misuse of genetic information while protecting the ability of health care providers to provide the best possible care to their patients. HR 493 also protects individuals who participate in research from having their genetic information, or the fact of their participation in a genetic research study, used in harmful ways by health insurers or employers.

Testimony of Kathy Hudson, Ph.D.
Director, Genetics and Public Policy Center
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Institute of Genetic Medicine & Department of Pediatrics
Johns Hopkins University

Before The House Energy and Commerce Committee
Subcommittee on Health
on
H.R. 493, The Genetic Nondiscrimination Act

March 8, 2007

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My name is Kathy Hudson and I am the Director of the Genetics and Public Policy Center at Johns Hopkins University, where I am also Associate Professor in the Berman Institute of Bioethics and in the Institute of Genetic Medicine. Established with a grant from The Pew Charitable Trusts, the Genetics and Public Policy Center works to help policy makers and the public better understand and respond to the challenges and opportunities arising from rapid advances in human genetics and its application to healthcare. Since our founding in 2002, the Genetics and Public Policy Center has conducted in-depth policy analysis and social science research on genetic testing and genetic technologies. This week the Center completed a survey of Americans' attitudes about genetic testing and I am delighted to share our new results with you today[1].

I have been involved in genetics research and genetics policy for many years and have had the pleasure of providing technical assistance and advice to many members and their staff during the crafting of genetic non-discrimination legislation over the last decade. I am delighted to see momentum growing for passage of legislation to prevent genetic discrimination and I appreciate the opportunity to testify today.

The Human Genome Project (HGP) was an historic international effort to decipher, letter by DNA letter, the genetic instruction book for our species. The Human Genome Project was more than a technological tour de force, and the results do more than satisfy biological curiosity. Researchers now have powerful tools to dissect the genetic, environmental, and lifestyle factors that contribute to health and disease, and our nation's robust biotechnology industry is translating those findings into new diagnostics and medicines to preserve health and prevent disease.

[1] This survey was administered online by the Genetics and Public Policy Center to a randomly selected, representative sample of American adults 18 years of age or older. The survey was fielded between February 27 and March 4, 2007 to 1,832 adults. Of these 1,199 responded, for a completion rate of 65%. The margin of error is +/- 2.7 percent. To correct for small sampling errors, the reported results were weighted with respect to U.S. benchmarks for age, gender, race/ethnicity, region, and education.

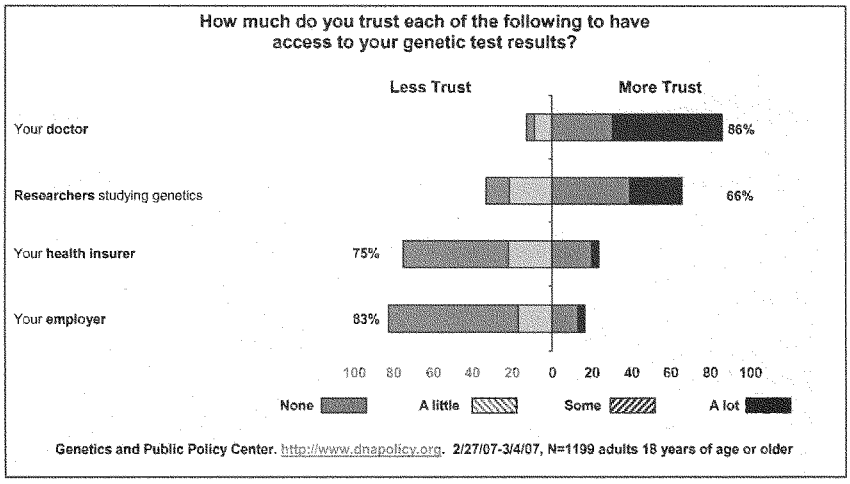
Today there are more than 1000 genetic tests available or in development. Tests are being developed for a wide variety of conditions but they have one thing in common: they provide information. Increasingly, this information can be used to inform personalized health care decisions. Within a decade, it may become common medical practice to test each one of us for our individual susceptibilities to common illnesses or our risk of adverse reactions to commonly prescribed medications. This knowledge will allow the use of individualized preventive care to maintain wellness and save countless dollars spent on trial-and-error prescribing of expensive or ineffective medicines.

Today, the American public is very enthusiastic about the promise of genetic medicine and supports the use of genetic testing in healthcare to learn about future risk of disease. Americans clearly understand the value of genetic testing to improve health care. In our survey, completed this week, we found that more than 90 percent of Americans support the use of genetic testing by doctors to identify a person's risk for future disease when there are treatments or medicines available, or to determine the risk of having a bad reaction to a particular medicine. A large majority of Americans (79 percent) also support the use of genetic testing by doctors to identify a person's risk for future disease even when there currently are no treatments or medicines available for that disease.

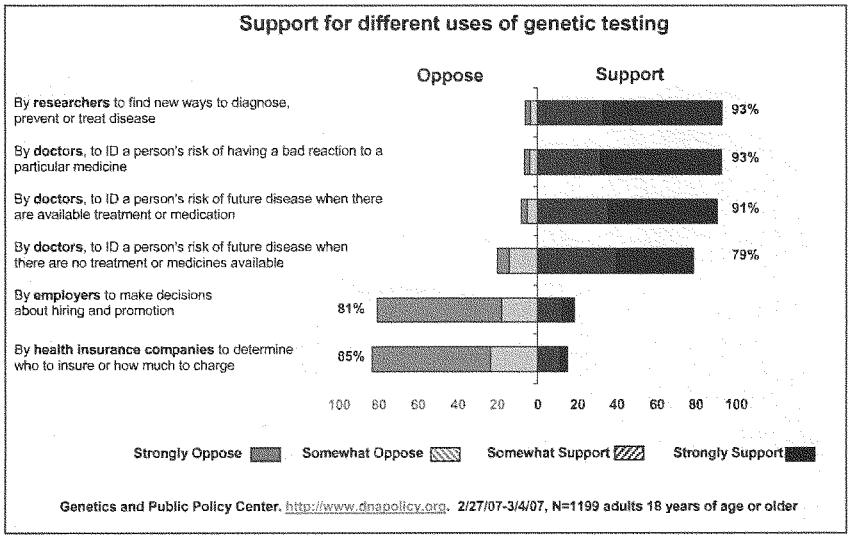
The public also is very supportive of biomedical research to find the genetic contributors to common complex diseases and develop safer and more effective medicines. In our survey, more than 90 percent support the use of genetic testing by researchers to find new ways to diagnose, prevent or treat diseases; two-thirds of Americans trust researchers studying genetics to have access to their genetic test results.

But growing uncertainty and fear threaten the future of genetic medicine. Citizens are increasingly concerned that genetic test results will be used against them in ways that undermine our fundamental values of fairness. Today, more than 90 percent of Americans are concerned that results from a genetic test that can tell patients whether they are at increased risk for a disease like cancer could be used in ways that would be harmful to them; nearly half of all Americans say they are *very* concerned.

There is ample evidence that many patients fear having their genetic information used to deny them health insurance or a job. As a result, patients may pass up genetic testing that could benefit their health, or they could go to great lengths to obtain genetic tests outside the usual health care channels to keep the information from their provider and insurer – paying out of pocket for genetic tests or attempting to keep genetic test results out of their medical records in ways that may jeopardize their care by withholding relevant information. While the public trusts their doctors and genetic researchers, they simply do not trust health insurers or employers to have access to their genetic information.



In our survey, we asked about support for or opposition to various uses of genetic testing, and heard clearly that Americans oppose the use of genetic testing by employers and insurance companies. Four out of five Americans oppose the use of genetic testing by employers to make decisions about hiring and promotion; even more (85 percent) oppose the use of genetic testing by health insurance companies to determine whom to insure and how much to charge. (Figure 2)



When asked specific questions directly relevant to this legislation, nearly all Americans (93 percent) believe that health insurers should not be able to use a person's genetic test results about increased risk of future disease to deny or limit insurance or charge higher prices. Similarly, 93 percent feel that employers should not be able to use this type of genetic test result to make decisions about hiring and promotion.

These fears about genetic discrimination are a significant factor in research. Just this week I was in Philadelphia conducting focus groups to learn how ordinary citizens would view a proposed large population study to understand the genetic, environmental, and lifestyle factors that contribute to heath and disease. By and large, we heard substantial enthusiasm about the study and hopes that such a study could help others at some point down the line. But their enthusiasm and altruism was deeply eroded by concerns about the privacy of genetic information and its possible misuse.

Researchers in a range of genetic studies have reported that potential research participants share this fear of what might happen to their genetic information. The inability of researchers to provide solid evidence of protections against genetic discrimination discourages research participation and endangers genetic research. When citizens give of themselves to help others and to advance biomedical research, don't we at least owe them a solid guarantee that their genetic information will be not be misused?

These issues were anticipated early on in the Human Genome Project and a number of steps already have been taken to put limited protections in place. With the passage of the Health Insurance Portability and Accountability Act (HIPAA) in 1996, Congress put in place some restrictions on group health insurers' use of health-related information in determining eligibility for benefits and in setting premiums. Congress specifically recognized and listed genetic information as protected health information. Subsequently, in promulgating privacy regulations called for by HIPAA, the Department of Health and Human Services made clear that access to and disclosure of genetic information is protected. But there are gaps in patient protections both in the group market and more notably in the individual market.

In the workplace setting, the EEOC has interpreted the Americans with Disabilities Act to provide some protections from the use of genetic information by employers, but the extent of those protections is largely untested and unclear.

HR 493 goes a long way toward filling the gaps in current law and calming a wary public by making clear that genetic information that is revealed through testing cannot be used to deny insurance to or otherwise prevent an unaffected individual from obtaining the insurance they need. Nor can an employer use such information to discriminate on the job.

I would like to focus my remaining comments on the impact of HR 493 on the provision of healthcare and the conduct of research.

How Does HR 493 Affect Provision of Healthcare?

Some opponents of HR 493 have suggested that the bill would impede the ability of healthcare providers to collect family history information, to request or recommend genetic testing, and to use this information to provide the best possible care to their patients. This is not the case.

HR 493 very clearly and very specifically safeguards the ability of healthcare providers to use the latest genetic tests and genetic medicines to take care of their patients. Indeed, section 101 (c) (2) and section 102 (c) (2) state explicitly that the language of the bill "shall not be construed to limit the authority of a health care professional who is providing health care services with respect to an individual to request that such individual or a family member of such individual undergo a genetic test."

Let me add that this protects all healthcare professionals, irrespective of their employer or association with a particular plan. Section 202 (b) (2) explicitly exempts health or genetic services offered by an employer from the prohibition on requesting genetic information. This exemption is echoed for health or genetic services offered by employment agencies, labor organizations, and training programs in sections 203, 204, and 205.

Thus, by restricting the discriminatory use of genetic information and expressly protecting the ability of healthcare providers to collect and use genetic information in the provision of patient care, HR 493 protects and nurtures the integration of genetics into medicine to benefit patients.

How Does HR 493 Affect Research?

A substantial impetus for HR 493 was the documented fear of genetic discrimination and its effect on research. It is critical that the bill protect the research enterprise and those that volunteer to participate in research studies. I am convinced that HR 493 protects both research and the research participants who are so vital to finding the tests and treatments of tomorrow.

HR 493 has solid and well-reasoned protections for research. First, by providing strong protections against the misuse of genetic information, HR 493 allows researchers to explain clearly to potential research participants that it is simply against the law for health insurers or employers to use genetic information to alter health insurance coverage or affect employment. The impact of this legal change will be substantial. Second, Section 209 (a) (4) of HR 493 includes language making explicit that nothing in the bill limits the ability of a Federal department or agency to conduct or sponsor occupational or other health research that is in

compliance with Federal human subjects research protections (45 CFR 46). And third, in the employment context, there are specific provisions addressing genetic monitoring to assess chromosomal or DNA damage caused by toxic exposures in the workplace.

In addition to preventing the misuse of genetic information collected as part of a research study, HR 493 offers further protection for research participants. Some are concerned that the mere fact of participation in a genetics research study might be construed by insurers or employers as indicating a heightened genetic risk and might therefore be used to the detriment of the research participant. HR 493 includes restrictions on health insurer and employer use of information about an individual's "request for or receipt of genetic services." Genetic services are defined as (A) a genetic test; (B) genetic counseling (including obtaining, interpreting, or assessing genetic information); or (C) genetic education. Therefore, participation in a genetic research study would be receipt of genetic services and the fact of a person's participation in a genetic research study could not be used to discriminate against them. I believe this language provides strong protections for research participants while preserving the ability of researchers to conduct their studies.

Conclusion

HR 493 prevents the misuse of genetic information while protecting the ability of health care providers to collect family history information, perform genetic tests, and use genetic information to provide the best possible care to their patients. HR 493 also protects individuals who volunteer to participate in research from having their genetic information, or even the fact of their participation in a genetic research study, used in harmful ways by health insurers or employers.

More than three-quarters of Americans believe there should be a law that prevents employers from using genetic test results about risk of future disease to make decisions about hiring and promotion; three-quarters also believe there should be a law to prevent health insurers from using genetic test results about risk of future disease to deny or limit insurance or charge higher prices. The message is clear.

A strong U.S. research and development enterprise is necessary but not sufficient for us to realize the future of personalized genetic medicine. We must also put in place public policies that keep pace with the science and ensure that genetic information is used for benefit and not for harm. We will scare Americans away from these life-saving technologies if they are not confident in the confidentiality of their genetic information.

When a woman goes to her doctor to discuss the possibility of having a genetic test to learn whether she has an increased genetic risk for a disease, she has many important issues to consider, including what the results will mean for her medically and emotionally. How will the test results affect her treatment? What will the test results mean for her family? And what it will mean for her, personally, to have this information about her own genome? It is my hope that soon, very soon, doctors will be able to tell their patients that while there is much to consider when deciding to have a genetic test, the threat that genetic test results could be used to deny health insurance or a job is not one of them.

The need for Congress to act grows with every new test developed and with every patient who decides to forego or delay genetic testing because of discrimination concerns. Thank you for taking up consideration of HR 493.

Testimony on

Genetic Information and Testing

By

William Corwin, M.D.
Medical Director, Clinical Policy
Harvard Pilgrim Health Care
on behalf of
America's Health Insurance Plans

Before the
U.S. House Committee on Energy and Commerce
Subcommittee on Health

March 8, 2007

I. Introduction

Mr. Chairman, Mr. Deal, and members of the subcommittee, my name is Dr. William Corwin. I am the medical director for clinical policy at Harvard Pilgrim Health Care. Harvard Pilgrim Health Care is a not-for-profit health plan that provides a variety of insurance plan options to more than a million members in Massachusetts, New Hampshire and Maine. Harvard Pilgrim provides innovative approaches to health improvement and disease management, unique online tools that speed and simplify key transactions for employers and providers, and personalized health support.

Harvard Pilgrim was named the #1 health plan in America in three consecutive years according to a joint ranking by *U.S. News & World Report* and the National Committee for Quality Assurance (NCQA). The November 6, 2006 edition of *U.S. News & World Report* ranked the nation's best health plans and determined that Harvard Pilgrim continues to lead the country for member satisfaction and quality of care. Harvard Pilgrim is the only health plan to earn the nation's top rating from NCQA three years in a row. Harvard Pilgrim's HMO and PPO plans have been recognized by J.D. Power and Associates for providing health plan members with an outstanding member experience for a third consecutive year.

Harvard Medical School and Harvard Pilgrim Health Care jointly sponsor The Department of Ambulatory Care and Prevention (DACP). This is the nation's only medical school department that is jointly sponsored by a health plan. The DACP is actively engaged in both research and teaching. The DACP leads in the creation and dissemination of new knowledge and skills essential to maximizing the health of defined populations within available resources. Research conducted by the DACP is routinely vetted through the Harvard Medical School Institutional Review Board process.

I appreciate this opportunity to testify about issues relating to genetic information and testing, including H.R. 493, the "Genetic Information Nondiscrimination Act of 2007" (GINA). I am testifying today on behalf of America's Health Insurance Plans (AHIP), which is the national association representing nearly 1,300 health insurance plans providing coverage to more than

200 million Americans. AHIP's members offer a broad range of products in the commercial marketplace – including health, long-term care, dental, disability, and supplemental coverage – and also have demonstrated a strong commitment to participation in public programs.

Health insurance plans are working on a daily basis to promote the appropriate use of genetic tests to help clinicians and patients make informed health care decisions and improve health outcomes. We agree with the sponsors of H.R. 493 that health care consumers should not face discrimination on the basis of their genetic makeup and that genetic information should be protected from unauthorized disclosure. Our policies and programs reflect this belief.

Our testimony today will focus on three broad areas:

- examples of how health insurance plans are promoting the appropriate use of genetic tests to improve patient care;
- opportunities for improving H.R. 493, the "Genetic Information Nondiscrimination Act of 2007"; and
- our support for strong protections with respect to nondiscrimination and confidentiality of genetic information.

II. Improving Patient Care Through the Appropriate Use of Genetic Tests

Health insurance plans are strongly committed to helping their enrollees receive the highest quality care possible. Through early detection, disease management programs, and other quality improvement initiatives, we are working on a daily basis to identify individuals who can benefit from early intervention to guide patient-centered care and choices while supporting the best evidence-based treatment for specific illnesses and diseases. Genetic information, including the results of genetic tests, is just one more sophisticated source of data that clinicians and health

insurance plans are using to ensure that patients receive appropriate preventive care, coordination of services, and early treatment for their medical conditions.

Health insurance plans encourage appropriate genetic testing for individuals who are at risk of certain genetic conditions for which there are specific interventions for prevention or treatment. Such tests can provide information that may positively affect the course of an individual's treatment. The following are several examples of how genetic tests are being used to improve patient care:

- According to guidelines issued by the National Institutes of Health (NIH), the treatment for hepatitis C patients should be extended – from 24 weeks to 48 weeks of therapy – but only in cases where a viral genotype guide has been identified in an individual. In this situation, a genetic test can determine whether the patient could benefit from an additional 24 weeks of therapy and thereby help the clinician prescribe a more effective course of treatment. The health insurance plan will need to know whether the genetic test was performed in this situation in order to authorize and/or pay for the extended course of therapy for the individual.

- In February 2007, the Food and Drug Administration (FDA) approved a new genetic test, a MammaPrint, which indicates whether a woman is likely to have a breast cancer relapse. This test allows physicians to tailor therapy for individual patients and administer chemotherapy to only those patients who would benefit. At the same time, the test allows physicians to identify patients who would not benefit from chemotherapy and should not be subjected to this risky and costly treatment. This new test will help guide the treatment of roughly 100,000 women each year who are diagnosed with early stage breast cancer.

- Breast cancer patients can benefit from HER-2 genetic tests that indicate whether their tumors would be responsive to herceptin therapy. Significantly, this test also allows physicians to identify patients who would face adverse side effects, including increased risk of heart disease, if they received herceptin therapy that is not appropriate given their genetic makeup.

- Another test, the Cytochrome P450 enzyme, is genetically coded. The identification of the presence or absence of this genomic marker enables a physician to evaluate a patient's ability to process many different medications, adjust dosages intelligently, and avoid potential adverse drug reactions in patients who either metabolize a drug quickly or do not metabolize a drug at all. This test also is used to determine how children with certain forms of leukemia will respond to various doses of chemotherapy. Health insurance plans may request that this test be performed before authorizing a course of therapy or treatment to ensure that appropriate care is being provided to meet the patient's individual needs.

- Genomic signatures can be used to drive gene profiles from cell-lines that predict drug sensitivity for difficult-to-treat malignancies such as lung cancer. Genomic signatures will direct the choice of drug therapy as determined by the tumor's biology and not a "best guess" about what "might" work in an individual's situation.

To help patients understand the appropriate use of these and other genetic tests, health insurance plans are partnering with physicians and other providers to ensure that enrollees have access to informational materials about the impact of genetics on health care. This consumer education is helping to increase patient awareness about the availability of coverage for genetic tests and services as well as treatments and therapies that can be used to combat and treat genetic diseases and conditions. The value of this information can reduce unneeded anxiety about possible gene mutations or genetic diseases and conditions.

Health insurance plans are using genetic test results to promote preventive screening and disease management programs. These programs can help to improve health care for individuals who have tested positive for a genetic disease or who have a family history of a specific disease or condition. For example, individuals who have the gene for the familial form of colorectal cancer can receive coverage for more frequent preventive screenings. As scientists acquire a greater understanding of the role genes play in disease and develop more genetic therapies and possibly even cures, preventive screening and disease management programs can be tailored to improve outcomes for individuals. This ability will become even more important in the future.

Individuals also benefit from research projects that health insurance plans conduct to examine the genetic and environmental factors that influence common diseases such as heart disease, cancer, diabetes, high blood pressure, Alzheimer's disease, and asthma. By combining the genetic, health, and survey information from hundreds of thousands of members into databases, researchers hope to gain a deeper understanding of what combinations of genes and environmental factors influence the risk of complex diseases.

Such research projects meet the highest scientific standards and comply with the legal requirements for privacy and confidentiality, including the requirements applicable to federally-funded research projects under HIPAA (e.g., 45 C.F.R. 164.508, 512(i)) and other applicable legal provisions. One example is a project being conducted by another AHIP member, Kaiser Permanente of Northern California's Division of Research. In that project, individual participation in the research is completely voluntary and individual genetic information will not be used in genetic studies without written consent. The data will be used only for research purposes and ultimately is expected to yield findings that will enable the medical community to be more precise in pinpointing the causes of disease and tailoring treatment for patients.

III. Opportunities to Improve H.R. 493

We appreciate the interest many subcommittee members have shown in passing additional legislation addressing the use and disclosure of genetic information. As you consider such legislation, we urge you to fully evaluate the implications of any additional requirements or prohibitions and ensure that new legislation does not unnecessarily restrict the use of information needed to promote appropriate health care decision-making.

Working through AHIP, our industry association, we have reviewed H.R. 493 and identified several areas where we believe changes are needed to ensure that genetic information can continue to assure appropriate coverage decisions and be available to improve the quality of patient care. We would like to publicly state that we do not oppose the bill and agree with its

intent. However, once enacted, the bill will be interpreted by clinicians, non-clinicians, individuals, lawyers, courts, and other interested persons who can take various interpretations of Congress' intent and how the requirements can apply in various settings. To avoid any confusion, health insurance plans would like to engage subcommittee members in a dialogue about our suggestions for clarifying the statutory language of the bill. We respectfully offer the following issues for your consideration.

- **Medically-indicated testing should be encouraged to promote consumer access to appropriate coverage and treatment.**

  As currently drafted, section 101 of the bill could limit consumer access to life-saving treatments because it prohibits health insurance plans from "requesting or requiring" an individual or a family member of an individual to undergo a genetic test. This prohibition can be read as restricting the ability of a health insurance plan to request this information, even when it is needed to determine the appropriate course of treatment and evaluate the patient's eligibility for coverage.

  As noted in the previous section, a genetic test is needed to determine whether hepatitis C patients could benefit from an additional 24 weeks of therapy under NIH guidelines. However, by prohibiting plans from requesting or requiring this test, H.R. 493 may cause some individuals to forego coverage for the extended therapy that is needed to effectively treat their particular condition.

  Looking to the future, unforeseen advances in medical treatment and technologies may lead to many additional circumstances where health insurance plans will need to request genetic tests to determine whether customized therapies or treatments are warranted. Therefore, we urge the subcommittee to consider changes that would allow proper uses of genetic tests while at the same time meeting the bill's original goal of prohibiting genetic discrimination.

- **Health insurance plans should be allowed to request "genetic tests" to promote preventive screening and disease management.**

Another concern is that this legislation would prevent health insurance plans from continuing to use genetic tests to promote preventive screening and disease management programs.

We are proud of the success health insurance plans have achieved in promoting preventive health care services to keep Americans healthy, detect diseases at an early stage, and avoid preventable illnesses. Plans also have been proactive in developing innovative disease management programs to improve patient care and health outcomes for persons with diabetes, congestive heart failure, and other chronic conditions.

Because of these private sector initiatives, millions of Americans are healthier and enjoying a higher quality of life. Congress should be making every possible effort to support these initiatives. Unfortunately, H.R. 493 could stifle health insurance plans from utilizing genetic tests to identify patients who may benefit from specific types of preventive screening or disease management services.

For example, a person who has the gene for the familial form of colorectal cancer could benefit from earlier or more frequent screenings for the disease. As genetic science advances over the next decade and beyond, health insurance plans will have a legitimate need to use genetic testing to identify these persons and ensure that they receive the necessary screening and early intervention to detect and treat cancers for which they are highly susceptible.

Current law allows health insurance plans to use genetic testing in this manner, but H.R. 493 could prevent plans from taking such proactive measures on behalf of their enrollees. We urge the committee to change the bill to ensure that it does not unintentionally undermine preventive health care services and disease management programs.

- **A clearer, more precise definition of "genetic information" would promote optimal patient care and help avoid unintended consequences for consumers.**

We also are concerned that H.R. 493 includes an excessively broad definition of the term "genetic information." As currently written, this definition could apply to diseases, tests, and conditions that are completely unrelated to genetics.

Another problem is that the bill's definitions arguably could apply to certain conditions – such as obesity or high cholesterol – that are not genetic, but may be linked to a person's family history. Even though there is no connection to a specific gene for these conditions, the bill in its current form could be interpreted to prevent health insurance plans from requesting tests that could help patients avoid or overcome health problems caused by obesity or high cholesterol.

These are serious issues with far-reaching implications for health care consumers. As this bill moves through the legislative process, we urge the subcommittee to define "genetic information" with greater clarity and precision.

- **The threat of litigation can be alleviated by clarifying that Title II of the bill, encompassing employers and unions, does not cover the administration and operation of employer-sponsored group health plans.**

Although the bill includes separate titles addressing health insurance issues (Title I) and employment issues (Title II), the legislative language of Title II could be interpreted to include the terms of an employer-sponsored group health plan as an employer practice that could be the basis for a discrimination complaint. Specifically, section 202 states that it is an unlawful employment practice for an employer to "discriminate against any employee with respect to the compensation, terms, conditions, and privileges of employment." This language can be interpreted as applying to a health benefits plan or health coverage sponsored or offered by an employer. Some employers may be discouraged from offering employee health benefits to avoid the threat of litigation. It is our understanding that the Title II provisions were not intended to cover health benefits plans and we suggest that the language be clarified to ensure that employer-sponsored group health plans are not covered under the Title II language.

We also would like to bring certain technical issues to the subcommittee's attention. It is our understanding that the sponsors of H.R. 493 do not intend for the bill to cover long-term care products. Also, the bill may be read to effectively create "two classes" of health information, creating barriers to optimal patient care and the advancement of a national health information infrastructure. AHIP is communicating with subcommittee members and staff about these and other significant issues.

IV. Industry Support for Nondiscrimination and Privacy Protections

It is important for the subcommittee to understand that genetic information is not used to deny or cancel coverage or set premiums. At the same time, health insurance plans are accustomed to and understand the importance of protecting the privacy and confidentiality of individually-identifiable health information, including genetic information. Our industry's practices reflect our strong support for provisions of current law that: (1) prohibit discrimination against individuals based on their genetic information; and (2) protect the confidentiality of patient-identifiable genetic information.

The federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) prohibits employers and health insurance plans in the group market from using the results of genetic tests to deny coverage or set different premium rates for individuals who participate in group health plans. HIPAA specifically prohibits group health insurance plans from:

- refusing to cover employees or their family members based on genetic information;
- refusing to renew coverage based on genetic information;
- charging employees and their family members higher premiums based on genetic information; and

- canceling coverage based on genetic information.

In addition to providing these nondiscrimination protections, HIPAA established an effective framework for health insurance plans, health care providers, and health care clearinghouses to protect individuals' health information. In addition, a number of state privacy laws impose similar restrictions on the use and disclosure of health and genetic information by health insurance plans.

The following examples highlight some practical examples of how these privacy protections apply in real-life settings:

- HIPAA prohibits health insurance plans or health care providers from disclosing information about an individual's genetic tests to an employer who sponsors a health insurance plan.

- HIPAA permits health insurance plans and health care providers to use and disclose genetic information when needed for the individual's treatment.

- HIPAA permits health insurance plans and health care providers to use and disclose genetic information when needed for coverage determinations – such as to determine whether coverage for a genetic test or genetic service will be authorized or paid for by a health insurance plan.

- HIPAA permits individuals to authorize a health insurance plan or health care provider to disclose their genetic information to a person who would otherwise not be entitled to receive the information (e.g., to a family member interested in learning about the individual's genetic conditions).

V. Conclusion

Thank you for considering our perspectives on these important issues. Health insurance plans are strongly committed to ensuring that genetic information is used to help clinicians and patients make informed health care decisions and, at the same time, maintaining strong protections in the areas of nondiscrimination and confidentiality. We appreciate this opportunity to testify and we stand ready to work with the subcommittee on this and other health care priorities facing our nation.

Summary

For more than a decade, experts have called on Congress to enact comprehensive legal prohibitions on genetic discrimination in health insurance. Fear of genetic discrimination can discourage patients from undergoing genetic testing or participating in genetic research studies. Such fear threatens to deter advances in the field of genetic testing and may limit the realization of benefits of genetic testing.

A prohibition on genetic discrimination challenges a key construct in medically underwritten health insurance: in return for premium payments, insurers promise to protect consumers against the cost of unknown future medical risks. Insurers use medical underwriting to distinguish known risks that will not be covered. Eventually genetic testing may render this construct obsolete and all people may be able to discover their future health risks, rendering us all "uninsurable." For today, however, GINA would protect our genetic information because its importance is so profound. By protecting our insurability, GINA also makes it more likely that advances in genetic science will discover more effective treatments, cures, and preventive therapies.

Recent research examined medical underwriting practices of individual health insurance companies in response to genetic information. An examination of actual instances of genetic discrimination in the individual market is impractical because the science of genetic testing is young and relatively few individuals have undergone predictive genetic testing. Our research asked individual health insurers to medically underwrite hypothetical applicants. Four pairs of applicants were presented; within each pair, one applicant had received a positive genetic test result indicating elevated risk of future disease. In seven instances, five of the 23 responding medical underwriters said they would take an adverse action based on genetic information. They would deny coverage, surcharge premiums, and impose exclusion riders to limit covered benefits.

Underwriters were also asked what actions they would take based on an applicant's receipt of genetic services. Specifically, they were asked to consider an applicant with a *BRCA1* mutation whose doctor had discussed or recommended preventive surgery to reduce her future risk of cancer. Thirteen underwriters responded to this question. Of those, five said they would take an adverse action based on discussion of risk reducing options. Ten said they would act on a physician's recommendation of such options. Again, underwriters would deny coverage, surcharge premiums, or impose exclusion riders to limit covered benefits.

Congress and 43 states have enacted laws to prohibit genetic discrimination in health insurance, at least in some instances. Federal legislation is needed to ensure comprehensive protection against all forms of discrimination in all health insurance coverage – whether employer sponsored or individual, and whether regulated by states or the federal government.

Testimony of Karen Pollitz
Research Professor
Georgetown University Health Policy Institute
on
Genetic Discrimination in Health Insurance

U.S. House of Representatives
Committee on Energy and Commerce
Subcommittee on Health

March 8, 2007

Chairman Pallone, Representative Deal, and Members of the Subcommittee, thank you for this opportunity to testify on HR 493, the Genetic Information Nondiscrimination Act (GINA) of 2007. My name is Karen Pollitz. I am a health policy researcher and adjunct professor of public policy at Georgetown University. My field of expertise is private health insurance regulation, and my remarks today will focus on issues addressed in Title I of HR 493, which prohibits genetic discrimination in health insurance, as well as on findings of a recently completed study of medical underwriting and genetic information in the individual health insurance market.

For more than a decade, scientific and public policy leaders, including the Secretary's Advisory Committee on Genetics, Health, and Society, have called on Congress to enact comprehensive legal prohibitions on health insurance discrimination:

> "[The Committee] heard from many Americans who are concerned about the misuse of genetic information by third parties, such as health insurers and employers, and the potential for discrimination based on that information. Many stated that fear of genetic discrimination would dissuade them from undergoing a genetic test or participating in genetic research studies. Others stated they would pay out of pocket for a genetic test to prevent the results from being placed in their medical record. Such concerns are a deterrent to advances in the field of genetic testing and may limit the realization of the benefits of genetic testing."[1]

Without question, a prohibition on genetic discrimination challenges a key construct in medically underwritten health insurance. In return for premium payments, insurers promise to protect consumers against the cost of unknown, future medical risks. Insurers use medical underwriting to distinguish known risks that will not be covered. Eventually, scientific advances may render this construct obsolete, and all people will be able to discover one or more of our future health risks through genetic testing – rendering us all "uninsurable." By protecting our

insurability, however, GINA also makes it more likely that the medical benefits promised by genetic science come to pass with the discovery of more effective treatments, cures, and preventive therapies for many serious and expensive health conditions.

Current law prohibitions are incomplete

Congress and the states have already gone a long way toward ending genetic discrimination in health insurance, though work remains to be done. There is not yet comprehensive protection against genetic discrimination in health insurance. Comprehensive protection will prevent all health plans and health insurers in all markets from turning people down, charging them more, or excluding or limiting covered benefits based on genetic information. Only federal legislation can accomplish this goal.

In 1996, Congress enacted the Health Insurance Portability and Accountability Act (HIPAA), setting federal minimum standards for private health insurance, including a requirement that employer-sponsored group health plans may not exclude participants based on genetic information or other factors relating to health status. HIPAA also prohibited group health plans from imposing pre-existing condition exclusion periods based on genetic information. However, HIPAA did not prohibit individual market health insurers from underwriting on the basis of genetic information, nor did it limit insurers in any market from varying premiums on that basis.

Since HIPAA, 43 states have prohibited use of genetic information by individual market health insurers. (See Appendix A) Most have enacted statutory prohibitions, which vary. Some state laws, for example, prohibit medical underwriting based on genetic test results, but not on family history. A few states prohibit insurers from denying coverage based on genetic information, but permit premiums to be surcharged. Interestingly, most state insurance regulators would enforce a broader prohibition on genetic discrimination than plain statutory language might

otherwise indicate. For example, most say insurers cannot underwrite based on family history, even when this is not specifically included in the state law definition of genetic information. However state laws do not apply to group health benefits offered by so-called self-insured employer plans because a federal law called ERISA preempts state regulation in this area.

Comprehensive prohibition of genetic discrimination in health insurance is needed.

Some in the insurance industry have testified that federal legislation is not necessary, arguing that there is no evidence that insurers engage in genetic discrimination.[2] According to one industry expert,

> "There is good research out there showing that people *believe* employers, health insurers, doctors and the family dog are using genetic information against them. [But] health insurers are not using genetic information. There is a very real public fear but it is unfounded. That information is not being used against people today."[3]

However, it is unlikely that medical underwriters in health insurance have had many opportunities to discriminate based on genetic information. The science of genetic testing is still young, and relatively few individuals have undergone predictive genetic testing in the U.S. For example, genetic testing for hereditary breast/ovarian cancer via *BRCA1 and BRCA2* testing is one of the better known and more widely used predictive genetic tests. Since this genetic test became clinically available in the mid 1990s, about 75,000 individuals have been tested through the commercial lab which holds the patents on these genes, and approximately 9,000 have received positive test results.[4] Many, if not most of those patients with positive test results likely were insured by employer-sponsored group health plans, where discrimination based on health status is already largely prohibited.

Even so, as causative genes associated with increased susceptibility to common diseases, such as asthma, heart disease, and cancer are identified, the number of tested individuals will grow considerably. It is therefore important to understand how health insurers would respond to

genetic information about applicants for coverage when they encounter this information in the medical underwriting process.

Background on Medical Underwriting

Individual health insurance plays a small but important role in our nation's system of health coverage. People often turn to this market when they cannot get health benefits from an employer or when they are ineligible for public programs such as Medicare or Medicaid. In 2005, over 17 million people in the U.S. were covered by individual health insurance, or 6.6 percent of the non-elderly population.[5] On average, over a three-year period, one in four adults buys or seeks individual coverage.[6]

Individual health insurance is medically underwritten in most states. This means applicants for coverage must submit information about their current and past health status – for example, whether they have been diagnosed with medical conditions such as diabetes, dates of and reasons for recent physician visits, names and dosages of recently prescribed medications, etc. Health insurance applications typically do not include specific questions about genetic test information nor about family health history.

On as many as half of individual health insurance applications, underwriters make a decision to issue or decline coverage based solely on health status information provided on the application.[7] For other applicants, additional information may be required. All applications for medically underwritten health insurance policies require written consent to release any medical records and to submit to further medical examinations that may be requested. Most often additional medical information will be sought directly from the applicant (for example, a telephone interview to determine results of a recent pap test), or her physician. Less frequently, applicants may be required to take a physical examination or submit samples of urine, blood, or saliva for testing. A 2001 report on medical underwriting practices found that in the course of 420 applications for coverage studied, underwriters requested further specific medical histories

179 times, attending physician statements and/or copies of patient medical records 140 times, samples of blood, saliva, or urine for laboratory testing 46 times, and paramedic physical examination of the applicant 21 times.[8] Other experts on individual health insurance market underwriting suggest patient medical records are typically requested on 20 percent of applications, while a very small portion of insurers (estimated at fewer than one-in-ten) may request records on more than 40 percent of applications.[9] It is in this additional investigation of an applicant's medical history and health status that information about genetic testing is likely to be discovered. Underwriters can come across medical information they did not specifically seek. Once disclosed, however, they are obliged to consider, evaluate, and act upon all available information.

The actions underwriters may take on an application fall into three main categories.

- Coverage may be offered, or the applicant may be turned down.
- If offered, coverage may be priced using a standard rate premium, or a premium surcharge may be applied.
- If offered, the policy may include all covered benefits, or certain benefits may be specifically limited or excluded. For example, the insurer may apply an exclusion rider,[1] or increase the policy's annual deductible.

Underwriter responses to genetic information

Last year, my colleagues and I partnered with Beth N. Peshkin, a senior genetic counselor and associate professor of oncology at Georgetown's Lombardi Comprehensive Cancer, to conduct a study of medical underwriting practices in the individual health insurance market as they relate to genetic information. Our team also worked with private risk management

[1] An exclusion rider is an amendment to the insurance policy that specifically excludes coverage for a named health condition. Sometimes exclusion riders also eliminate coverage for body parts or systems that a health condition might affect.

consultants to design and implement this study. This project was supported by a grant from the Nathan Cummings Foundation.

Professional medical underwriters from 23 insurers – some local and some multi-state – volunteered to participate in a survey about medical underwriting practices and genetic information. Survey participants were senior health underwriters from 23 companies that sell individual health insurance. Sixteen worked for national, commercial insurers that write coverage in multiple states; seven worked for nonprofit Blue Cross Blue Shield plans. The size of participating insurers varied, though according to data from the National Association of Insurance Commissioners, three of the participating insurers rank among the top ten health insurance companies based on national market share, and eight rank among the top 25 companies.[10] Participants and their employing insurers were promised anonymity.

Our survey asked participants to underwrite eight hypothetical applicants for coverage. The applicants were arranged in pairs that were almost identical except one person in each pair had received a positive genetic test result. For each pair of applicants, medical information was provided that would likely prompt further investigation by underwriters. The survey noted when genetic test result information was discoverable via patient medical records or other follow up inquiry. The hypothetical applicants presented in the survey were:

- Ann and Brenda -- healthy 29-year-old women who receive regular annual mammograms well before the age of 40 when such screening is recommended for the general population. Upon review of medical records, it is clear that both Ann and Brenda have a family history of breast cancer. In addition, Brenda has inherited a *BRCA1* mutation, meaning her lifetime risk of breast and ovarian cancer is significantly elevated, though not certain.
- Clarice and Donna -- 48-year-old women who are ten-year breast cancer survivors. Both women recently had preventive surgery to remove their ovaries. Upon review of medical records, it is clear that Donna's reason for undergoing surgery was a

genetic test result from 2003 which was positive for mutation in the *BRCA1* gene, meaning her lifetime risk of a second breast cancer is significantly elevated, but not certain.

- Evan and Fritz -- 52-year-old men in good health. Both receive regular blood tests to monitor blood iron levels. In follow up telephone interviews both men acknowledge a close family history of Hemochromatosis, though blood tests for both men have consistently been negative for elevated blood iron levels. Fritz has also undergone genetic testing with a positive result, meaning his blood iron levels may eventually increase and need to be managed.
- Galen and Howard -- 44-year-old men in excellent health. Both of their insurance applications disclosed a recent consultation with a cardiologist, and both take several nutritional supplements daily. Medical records indicate Galen sought his checkup after a neighbor his age died suddenly of a heart attack. Howard's visit was prompted by an online genetic testing company report that said he has gene variants that put him at risk for heart disease. The cardiologist questioned the validity of the tests and assured him the gene variants found are commonly observed in most people.

Survey participants were asked what underwriting action(s) they would take in response to each of the hypothetical applicants. Five of the 23 underwriters responded in seven instances that they would treat applicants differently because of their genetic information. For Brenda, the hypothetical applicant with a BRCA1 mutation, insurers # 7, #8, and #23 said they would, respectively, offer Brenda coverage at a surcharged premium, deny her application, and offer a policy with a rider excluding coverage for all diseases and disorders related to her breasts. For hypothetical Donna, a ten-year breast cancer survivor with a BRCA1 mutation, insurer #11 would reject her application. Insurer #1 said consideration of the application from hypothetical Fritz

would be postponed pending provision of additional medical information, while insurer #8 would deny Fritz's application. Finally, insurer #8 would postpone consideration of Howard's application pending provision of additional medical information.

In addition to these actions, in two other instances underwriters (for insurers #7 and #21) were uncertain as to the appropriate underwriting action and said they would need to consult their medical directors. (See Table 1)

The good news is that most underwriters said most of the time that they would not act based on genetic information. Most said this is because their company policy is to underwrite on the basis of a definitive diagnosis and treatment, and they do not underwrite on the basis of family history or genetic information in the absence of a diagnosis. Most underwriters believed their company policy had been adopted pursuant to laws prohibiting this practice. (Those from multi-state insurers said their company's policy would apply even in those states that have not yet enacted legislation.)

Nevertheless, survey findings are also consistent with patient and policymaker concerns that genetic discrimination in health insurance can happen today and could pose a problem in the future. When asked whether they would take adverse action based on genetic information in the absence of legal prohibitions, many underwriters answered yes.

Underwriter responses to genetic services

Legislation before you today also prohibits health insurance discrimination based on receipt of or request for genetic services – a term which includes genetic counseling to interpret or assess genetic information. Some patients with inherited risk of disease today have options – ranging from lifestyle changes to preventive therapies or surgery – to reduce that future risk and may consider those pursuant to genetic testing. As part of our research, we asked underwriters to participate in a follow up survey that also tested their reaction to genetic services. The follow up

Table 1. Underwriter Response to Hypothetical Applicants With Genetic Information
[Applicants *italicized* had positive genetic test results]

Insurer	Ann	*Brenda*	Clarice	*Donna*	Evan	*Fritz*	Galen	*Howard*
1						Pend. Unable to offer without diagnosis.		
2								
3								
4								
5								
6								
7		Premium surcharge (25%)						Unsure. Would refer to Medical Director.
8		Deny				Deny		Pend until further evaluation completed
9								
10								
11				Deny				
12								
13								
14								
15								
16								
17								
18								
19								
20								
21								Unsure. Would refer to Medical Director.
22								
23		Rider disease/disorder of breast						

Note: Table shows only those underwriting actions which differed between applicant pairs based on genetic information.

survey sought additional information about one of the hypothetical applicants with a *BRCA1* mutation, who would also have been counseled about options for reducing her inherited risk of breast and ovarian cancer. Underwriters were asked, "If Donna's medical records indicated her doctor had discussed or recommended options to reduce her risk of future breast cancers (for example, prophylactic surgery) what underwriting actions would you take on her application?"

Only 13 underwriters responded to these follow up questions. Of those, five indicated they would take an adverse action in response to Donna's doctor having discussed risk reducing

options, while ten of 13 said they would take an adverse action if the doctor recommended a significant medical procedure to reduce inherited risk. (See Table 2) Interestingly, when the same question was posed to state insurance regulators, most said their laws would also protect against genetic discrimination based on these kinds of patient-physician communications. (See Appendix B)

Table 2. Underwriting Actions for Donna Based on Interventions to Reduce Breast Cancer Risk (Counseled vs. Recommended)

Insurer	Underwriting Action	
	Doctor discussed prophylactic surgery to reduce risk	Doctor recommended prophylactic surgery to reduce risk
1		Postpone
2	Probably Rider	Probably Rider
4	Rate	Rate
6	Rider	Rider
7		Rider or Deny
10		Deny
11	Deny	Deny
12		Rider
14		
15		
16		Postpone
17	Deny	Deny
20		

Limitations of Methodology

The small number of self-selected survey respondents means results cannot be interpreted as representative of the entire health insurance industry. In addition, because the survey asked questions about only three genetic tests, results provide no information about how underwriters might respond to other types of genetic information or inherited risks. Other study design aspects may have biased results. For example, survey respondents came from a self-selected sample of those who participate in a professional underwriting study group and who tend to be more senior, expert, and informed about issues. In addition, the survey clearly identified the issue being studied, potentially biasing respondents to answer "correctly." On the other hand, survey

vignettes also made obvious applicants' genetic information. Therefore results do not shed light on how well underwriters recognize, or overlook, this information when they encounter it in practice. Nevertheless, the responses of so many mainstream insurers provide important insights into industry underwriting practices related to genetic information.

Policy implications

Industry experts and others have urged that health insurance discrimination based on genetic information happens rarely, if at all, today, and there is evidence to support this contention. The low incidence of predictive genetic testing in the general population is one key reason. In addition, prohibitions in more than 40 states may discourage insurers from actively seeking out information about applicants' genetic status or from acting upon such information when it is discovered in the course of underwriting. Most carriers surveyed said they do not underwrite based on genetic information.

However, findings showed that some individual market insurers would act on genetic information if they discovered it. In seven of the 92 decisions tracked by this study, an insurer used genetic information as the basis for their action to decline/postpone, limit coverage or surcharge premiums. These seven decisions were limited to five of the 23 insurance carriers and were spread across all four applicants with genetic information. One of these respondents expressed uncertainty as to the meaning of one of the genetic tests. Experts in the field of genetics have long called for "vigorous educational efforts" within the insurance industry to improve understanding about genetic information. Findings from this study suggest such education could be beneficial. Comprehensive federal legislation could also reinforce and strengthen state restrictions and promote a uniform standard within the health insurance industry to never use genetic information in medical underwriting.

From the insurer perspective, medical underwriting in individual health insurance is based on a key premise: the insurer promises to cover an individual's future health care risks, but

only if the applicant discloses known risks today. Public policy has insisted on an exception for genetic information – protecting this information, at least partially, because the clinical significance and promise of this science is so profound. Policymakers will have to decide how comprehensive and uniform protections should be. In so doing, they will have to consider the problem of health insurance discrimination in light of what genetic testing means for patients today and what it is likely to mean in the future. Advances in genetic science may make possible dramatic improvements in medicine and public health that can reduce or prevent the incidence of many serious and expensive health conditions. For that day to come, patients will need assurances that they can both learn their genetic status and take appropriate actions to reduce their risk and improve their health without endangering their insurability.

APPENDIX A
State Prohibitions on Use of Genetic Information in Medical Underwriting,
Individual Health Insurance Market

	Prohibited Underwriting Action											
	Application asks about:			Deny coverage based on:			Raise premium based on:			Exclusion rider based on:		
State	Family history	Received genetic services (incl. counseling or testing)	Positive genetic test results	Family history	Referred for genetic services (incl. counseling or testing)	Positive genetic test results	Family history	Referred for genetic services (incl. counseling or testing)	Positive genetic test results	Family history	Referral for genetic services (incl. counseling or testing)	Positive genetic test results
AL +						√			√			√
AK												
AZ +					x	√		x	√		x	√
AR +		x	x		x	x		x	x		x	x
CA +			√			√			√	√	√	√
CO		x	√	x	x	√	x	x	√	x	x	√
CT	x	x	x	x	x	√	x	x	√	x	x	√
DE				x	√	√	x	√	√	x	√	√
DC	x	x	x	x	√	√	x	√	√	x	√	√
FL		√	√	x	√	√	x	√	√	x	√	√
GA						√						√
HI	x	x	√	x	√	√	x	√	√	x	√	√
ID			√		x	√		x	√	√	√	√
IL +	x	x	√	x	x	√				x	x	√
IN		x	√	x	√	√	x	√	√	√	√	√
IA												
KS		√	√	x	√	√	x	√	√	x	√	√
KY			√		√	√		√	√	√	√	√
LA	√	√	√	√	√	√	√	√	√	√	√	√
ME				√	√	√	√	√	√	√	√	√
MD	x	x	√	x	√	√	x	√	√	x	√	√
MA	x	x	x	√	√	√	√	√	√	√	√	√
MI		√	√	x	x	x	x	x	x	√	√	√
MN		√	√		√	√		√	√	√	√	√
MS												
MO+		x	x	x	x	x	x	x	x	x	x	x
MT			√		x	√		x	√	x	x	√
NE												
NV		√	√	x	√	√	x	√	√	x	√	√
NH		√	√		√	√		√	√	x	√	√
NJ	√	√	√	√	√	√	√	√	√	√	√	√
NM				√		√	√		√	√		√
NY				√	√	√	√	√	√	√	√	√
NC		x	x	x	x	√	x	x	√		x	x
ND					x			x			x	

Prohibited Underwriting Action												
	Application asks about:			Deny coverage based on:			Raise premium based on:			Exclusion rider based on:		
State	Family history	Received genetic services (incl. counseling or testing)	Positive genetic test results	Family history	Referred for genetic services (incl. counseling or testing)	Positive genetic test results	Family history	Referred for genetic services (incl. counseling or testing)	Positive genetic test results	Family history	Referral for genetic services (incl. counseling or testing)	Positive genetic test results
OH			√			√			√			√
OK +				x	x	x	x	x	x	x	x	x
OR	√	√	√	x	x	√	√	√	√	√	√	√
PA	**	**	**	**	**	**	**	**	**	**	**	**
RI	x	√	√	x	√	√	x	√	√	x	√	√
SC				x	√	√	x	√	√	x	√	√
SD												
TN		x	√		√	√		√	√		√	√
TX				x	x	√	x	x	√	x	x	√
UT		√	√	x	√	√	x	√	√	x	√	√
VT				√	√	√	√	√	√	√	√	√
VA				x	√	√	x	√	√	x	√	√
WA	√	√	√	√	√	√	√	√	√	√	√	√
WV												
WI		√	√		√	√		√	√		√	√
WY				x	x	x	**	**	x	**	x	

Source: Statutory research by Georgetown University and responses of state insurance regulators to Georgetown survey conducted in May-June, 2006. Regulators in five states did not respond to the survey: California, Mississippi, New Mexico, New York, and Vermont. In these states, table only indicates prohibitions found in statutory language.

√ indicates prohibition found in state statute.

x indicates state regulator confirms practice is prohibited, but practice is not specified in statute.

** Regulator did not answer this question. No statutory prohibition found.

+ Additional state notes below:
Alabama prohibitions only apply to genetic information about risk of cancer.
Arizona prohibitions unless "applicant's medical condition and history and either claims experience or actuarial projections establish that differences in claims are likely to result from the genetic condition."
Arkansas prohibitions apply "except to the extent and in the same fashion as an insurer limits coverage or increases premiums for loss caused or contributed to by other medical conditions presenting an increased risk."
California prohibits insurers from denying "enrollment or coverage to an individual solely due to a family history of breast cancer, or who has had one or more diagnostic procedures for breast disease but has not developed or been diagnosed with breast cancer."
Illinois allows an insurer to "consider the results of genetic testing…if the individual voluntarily submits the results and the results are favorable to the individual."
Missouri prohibits insurers from inquiring "to determine whether a person or blood relative of such person has taken or refused a genetic test or what the test results of any test were…" except with approval of the applicant to consider this type of information.
Oklahoma prohibitions apply "except to the extent and in the same fashion as an insurer limits coverage or increases premiums for loss caused or contributed to by other medical conditions presenting an increased risk."

APPENDIX B
State Prohibitions on Use of Genetic Information in Medical Underwriting,
Individual Health Insurance Market

	Prohibited Underwriting Action					
State	Deny coverage based on:		Raise premium based on:		Exclusion rider based on:	
	Physician discusses risk reduction options	Physician recommends risk reduction options	Physician discusses risk reduction options	Physician recommends risk reduction options	Physician discusses risk reduction options	Physician recommends risk reduction options
AL +	x	x	x	x	x	x
AK						
AZ +						
AR +	x	x	x	x	x	x
CA +					√	√
CO	x	x	x	x	x	x
CT	x	x	x	x	x	x
DE	x	x	x	x	x	x
DC			x			
FL	√	√	√	√	√	√
GA	x	x				
HI	x	x	x	x	x	x
ID	x	x	x	x	√	√
IL +	x	x			x	x
IN	x	x	x	x	√	√
IA						
KS	x	x	x	x	x	x
KY	x	x	x	x	√	√
LA	x	x	x	x	x	x
ME	√	√	√	√	√	√
MD	x	x	x	x	x	x
MA	√	√	√	√	√	√
MI	x	x	x	x	√	√
MN	x	x	x	x	√	√
MS						
MO +						
MT	x	x	x	x	x	x
NE						
NV	x	x	x	x	x	x
NH	x	x	x	x	x	x
NJ	√	√	√	√	√	√
NM						
NY	√	√	√	√	√	√
NC	x	x	x	x	x	x
ND						

Prohibited Underwriting Action						
State	Deny coverage based on:		Raise premium based on:		Exclusion rider based on:	
	Physician discusses risk reduction options	Physician recommends risk reduction options	Physician discusses risk reduction options	Physician recommends risk reduction options	Physician discusses risk reduction options	Physician recommends risk reduction options
OH	x	x	x	x	x	x
OK +	x	x	x	x	x	x
OR	x	x	√	√	√	√
PA	**	**	**	**	**	**
RI	x	x	x	x	x	x
SC	x	x	x	x	x	x
SD						
TN						
TX	x	x	x	x	x	x
UT	x	x	x	x	x	x
VT	√	√	√	√	√	√
VA	x	x	x	x	x	x
WA	√	√	√	√	√	√
WV						
WI	x	x	x	x	x	x
WY	**	**	**	**	**	

Source: Statutory research by Georgetown University and responses of state insurance regulators to Georgetown survey conducted in May-June, 2006. Regulators in five states did not respond to the survey: California, Mississippi, New Mexico, New York, and Vermont. In these states, table only indicates prohibitions found in statutory language.

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Arizona prohibitions unless "applicant's medical condition and history and either claims experience or actuarial projections establish that differences in claims are likely to result from the genetic condition."
Arkansas prohibitions apply "except to the extent and in the same fashion as an insurer limits coverage or increases premiums for loss caused or contributed to by other medical conditions presenting an increased risk."
California prohibits insurers from denying "enrollment or coverage to an individual solely due to a family history of breast cancer, or who has had one or more diagnostic procedures for breast disease but has not developed or been diagnosed with breast cancer."
Illinois allows an insurer to "consider the results of genetic testing…if the individual voluntarily submits the results and the results are favorable to the individual."
Missouri prohibits insurers from inquiring "to determine whether a person or blood relative of such person has taken or refused a genetic test or what the test results of any test were…" except with approval of the applicant to consider this type of information.
Oklahoma prohibitions apply "except to the extent and in the same fashion as an insurer limits coverage or increases premiums for loss caused or contributed to by other medical conditions presenting an increased risk."

End Notes

[1] Letter to Secretary Tommy Thompson, May 3, 2001, at Hhttp://www4.od.nih.gov/oba/sacgt/ltr_to_secDHHS5-3-01.pdfH.
[2] See, for example, "Testimony of the HIAA on Genetic Testing," before the Senate Committee on Labor and Human Resources, May 21, 1998. See also "Testimony of John Rowe, M.D., Chairman and CEO, Aetna Inc.," before the House Judiciary Subcommittee on the Constitution, September 12, 2002.
[3] As cited in "Genetic testing: consumers fear it will be used to deny coverage and raise premiums" *Risk and Insurance,* April 14, 2003.
[4] http://www.myriadtests.com/provider/mutprev.htm
[5] U.S. Bureau of the Census and Bureau of Labor Statistics, 2006 Current Population Survey Annual Social and Economic Supplement.
[6] Duchon, L., et.al., "Security Matters: How Instability in Health Insurance Puts U.S. Workers at Risk," The Commonwealth Fund, December 2001.
[7] Personal communication with Kathy Thomas and Ben Chaput, risk management consultants specializing in the individual market, January 20, 2007.
[8] Karen Pollitz, Richard Sorian, and Kathy Thomas, "How Accessible is Individual Health Insurance for Consumers in Less-Than-Perfect Health?" Report to the Kaiser Family Foundation, June 2001.
[9] Thomas and Chaput, personal communication, January 20, 2007.
[10] National Association of Insurance Commissioners, "Accident and Health Insurance Industry 2004 Market Share Report by State and Countrywide," © 2005, NAIC. Accessed November 30, 2006. http://www.naic.org/documents/research_stats_market_share_health_sample.pdf

Testimony for the Record

The United States House of Representatives Energy and Commerce Committee Subcommittee on Health

Hearing on H.R. 493
"The Genetic Information Nondiscrimination Act of 2007"
March 8, 2007

by

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The National Association of Health Underwriters is a 20,000-member association of insurance professionals involved in the sale and service of health insurance, long-term care insurance and related products. Our members serve the insurance needs of over 200 million Americans. We would like to take this opportunity to present information on the health insurance underwriting process and the effect well-intended genetic discrimination legislation could have on the cost of health insurance as well as the cost impact on employers that are providing benefits such as health insurance for their employees. NAHU believes health insurance affordability is the most important component of access to health care.

Advances in the field of genetics have increased so dramatically that we are now able to clone animals. These dramatic advances have also provided new ways to check for the probability of certain illnesses. The possibilities for treatment and prevention of illness based on the availability of this new information are truly exciting.

In light of these rapid advances in the field of genetic research, some people have expressed concern about whether their genetic information might be used improperly to prevent them from obtaining health insurance or by employers for hiring or firing purposes. NAHU believes that health insurance or employment discrimination based on the genetic information of an otherwise healthy individual should be prohibited, provided that the definition of the "prohibited information" is carefully, clearly and narrowly defined. Inappropriate disclosures of all health information, not just genetic information, should also be prohibited, and regulations on disclosure should apply consistently to all types of health information. But any action taken on these prohibitions should be carefully balanced with the medical promise offered by genetics. In our race to protect the rights of Americans against unlawful discrimination and disclosure, we must be careful not to legislate away our ability to use advances in genetic science to improve our health and eradicate illness.

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) legislated many new protections for health insurance consumers; among those protections was a

provision stating that group health insurers cannot consider any employee's genetic information in the group health insurance underwriting process unless that genetic information has already resulted in a diagnosis. For example, if a generally healthy person had some genetic tests run to see if he had markers for any particular illnesses, that information would be prohibited from use. The law prohibits denial of benefits or increases in premium to individual members of a group health plan due to health status. HIPAA does not address the issue of genetic information in the individual health insurance underwriting process, nor does it address employment discrimination based on genetic information.

It is much more difficult to adequately spread insurance risk in the individual market than it is in employer-sponsored plans. This occurs for several reasons. First, in an employer-sponsored plan, employees are eligible to enroll for coverage when they are hired (following any probationary period) and, at most, once per year during an annual enrollment period. The employer also typically pays a significant portion of the cost of the coverage. For this reason, most people consider employer-sponsored coverage to be a good value and enroll for coverage when they are initially eligible, regardless of their health status. This results in employer-sponsored plans normally having a mix of insurable risks, particularly in larger plans.

In contrast, in the individual market, individuals are typically not eligible for health insurance coverage at a particular time and pay the cost of the coverage entirely on their own. As a result, they are much more likely to seek health insurance coverage when they think they need it, often called "adverse selection." These sicker individuals consume more health care and, because the cost of health insurance coverage is directly related to the cost of medical care by those who are insured, the cost of health insurance rises.

For this reason, it is important to determine the current health risk of those who apply for coverage by asking questions about health status. If legitimate health information is restricted from the underwriting process, the pool of people insured will gravitate toward those who are less healthy, and the cost of coverage will increase for everyone. This is

also the market most sensitive to those cost increases because, again, individual health insurance consumers do not have employers subsidizing the cost of their plans.

Many individuals and families will at some point in their lives purchase coverage in the individual health insurance market, and it is critical that the cost be affordable. If it is not, the ranks of the uninsured will rise, and costs in the small-group market will also increase as people attempt to game the system to somehow change their status from an individual market buyer to a "group."

The use of health status information in the underwriting process keeps costs down and offsets the impact of adverse selection. In states where individual health insurance policies must be issued without regard to health status ("guaranteed issue"), premiums are much higher, coverage choices are limited, and fewer insurance carriers operate in the individual health insurance market. A chart is attached that illustrates these cost differences.

To start out, it may be helpful to explain what underwriting is and why it is important.[1] Underwriting is a basic evaluation of risk. Applicants for all types of insurance go through a risk-evaluation process, or underwriting, as do applicants for credit cards, bank loans and mortgages. A bank would be very reluctant to issue a loan to someone who appears unlikely to be able to repay it, and an insurer would be unlikely to insure a house that was already on fire. If banks were unable to ask the information necessary to ensure the financial stability of applicants, they would either stop issuing loans or increase the interest rate to account for the increased likelihood of losses. Similarly, if an insurer couldn't ask whether a home was already on fire, the insurer would likely not insure homes or dramatically increase the cost to cover the cost of those who waited until their house was on fire to purchase coverage.

[1] A guide to understanding the health insurance underwriting process is included at the end of this testimony.

On the other hand, if the bank and insurer are able to ask the questions needed to accurately assess the risk of an applicant or homeowner, applicants may enjoy a "preferred" rate based on their good credit history, and homeowners may be able to receive discounts for certain safety and security features in their homes. Health insurance underwriting works the same way – the more information the underwriter has, the better the rates will be for most applicants.

Legislation under Consideration

The issue surrounding prohibition of discrimination by health insurance carriers due to genetic information has evolved over the past few years. Legislation to expand the prohibition on the use of genetic information in underwriting has resulted in a variety of opinions as to how genetic information should be defined. Using too broad a definition could disrupt and prevent normal underwriting procedures, resulting in unaffordable health insurance premiums for employers and individuals who purchase health insurance.

The first and primary issue regarding the definition of genetic information relates to **when** information should be considered genetic information. HIPAA prohibits discrimination by any individual within a group based on health status, including genetic information, in the absence of a diagnosis. During the 108th Congress, Representative Slaughter sponsored H.R. 1910. That bill excluded from the definition of "protected genetic information" information about physical exams of the individual, and other information that indicates the current health status of the individual. This exclusion is, unfortunately, not in H.R. 493. Genetic information about current health status may not only be very important to current diagnosis and treatment, but is also important to evaluation of risk for applicants in the individual health insurance market.

Because HIPAA did not adequately define **what** "genetic information" is, it is extremely important that any new legislation clearly specify what should be included in the term. NAHU believes the definition of genetic information should be limited to DNA and related gene testing done for the purpose of predicting risk of disease in asymptomatic or

undiagnosed individuals, and that it should clearly exclude such items as age, gender and information from physical exams and lab work, including items like cholesterol tests and blood pressure screening performed to detect symptoms, clinical signs or a diagnosis of disease.

As an example, a commonly performed lab test during a physical exam is cholesterol screening. Cholesterol screening is a metabolite test. Other legitimate genetic tests are also metabolite tests. Cholesterol screening is currently used as a diagnostic tool and, as such, a "high" result is considered a diagnosis. If physical exams and routine lab tests are not excluded as genetic tests, the status of an item such as cholesterol screening might have to be removed from the diagnostic category, along with the diagnostic code that allows millions of Americans to have their cholesterol-lowering medications covered by their health insurance.

Reduction in the ability to underwrite would have the same result it has had in the states that have tried it, including carrier withdrawal due to excessive losses, significantly reduced choice in benefits, few carriers from which to select coverage, and significantly higher cost for the coverage that is available.

Conclusion

Health insurance underwriting is a complicated process. It is a combination of art and science, and is highly dependent on not only the risk of the applicant but also on market conditions that may be beyond the applicant's control. The most important component of underwriting is complete information to allow for a thorough evaluation of risk.

Good underwriting at the inception of any health insurance policy won't prevent premium increases, but it does result in more stable rates over time. This stability allows families and businesses to plan and budget for their health care expenses, and helps keep coverage affordable and accessible.

There is no question that advances in genetics will increase exponentially in the coming decades. Changes in the accuracy and absolute predictability of the information that will be provided will also improve, and the use of this information to diagnose current illnesses may become as common as taking a blood pressure reading is today. It is extremely important that lawmakers recognize this changing dynamic and proceed thoughtfully on issues related to genetic discrimination, as well as privacy of all health information, to allow the medical field to advance treatments and find cures for those suffering with disease.

Additionally, lawmakers must realize the impact their actions will have on the cost of health insurance today and in the years ahead. Great care should be taken to craft legislation that is very specifically related to a prohibition of the use of genetic tests that are truly predictive in nature. Overly broad definitions will impede the normal underwriting process and increase the cost of coverage, resulting in reduced access to quality health care.

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Addendum A – Explanation of the Process of Health Insurance Underwriting

Underwriting of Health Plans

The Individual Health Insurance Market

Although most people who are insured are covered through employer-sponsored plans, some people do not have access to employer coverage and must buy in the individual health insurance market. The individual health insurance market offers a wide range of policy coverage options in many states, depending on the regulatory environment. Coverage is available in a wide range of deductibles and plan types, and most people can find a policy suitable for their needs, although coverage for maternity and mental health expenses is often limited and prescription drug benefits tend to be more restrictive than those found in the group market.

In most states, individual health insurance is rated based on the age and health status of the applicant and requires the completion of a health questionnaire. Occasionally, a paramedical examination and/or a blood and urine sample are required. Questions about genetic tests are not currently asked by any insurance carrier that we have been able to determine, although a small number of insurers ask questions about the medical history of the applicant's parents and siblings.

Applicants are asked a variety of questions about their current and past medical history, including height and weight, smoking status and details about recent physical exams, including the results of lab work. Complete information allows the underwriter to evaluate the risk of the applicant accurately and provides for greater rate stability. Any missing information can result in the applicant being turned down for coverage. At best, missing information will result in the underwriter assuming the worst, and the consumer will either pay more for coverage or have coverage excluded.

Depending on the state, an applicant for individual health insurance coverage will have coverage issued as applied for, have coverage issued with a rider for certain conditions or body parts, or have coverage "rated up" or issued at a premium higher than the standard rate. The majority of states don't have limits on rate-ups for individual coverage but, if an applicant's health history is such that a large rate-up is indicated, it is more likely that the person would be declined for coverage.

Applicants who are declined for coverage in many states are eligible for coverage through their state high-risk pool. In other states, there is an annual open-enrollment period for uninsurable individuals through one insurance carrier in the state. A few states guarantee coverage in the individual market, although the cost is high and choices significantly limited. Several states provide coverage through a "carrier of last resort," which means that the designated insurance carrier will accept an individual regardless of health status. Usually there is one month per year when this happens, although in some states applicants are accepted all year. A very small number of states have no option for medically uninsurable individuals.

Small Employer Groups of 2-50[1]

Although many people refer to employer self-funded health plans as ERISA plans, small-employer health insurance plans are also ERISA plans. Small employers can select from a variety of plans in most states, including HMOs, PPOs and indemnity plans. The selection depends largely on the regulatory environment in the state in both the small-employer **and** individual markets, and can vary dramatically from state to state.[2] Availability of coverage is also impacted by the location of the business. In general, rural businesses have less selection than businesses in metropolitan areas, largely due to the reluctance of rural providers to participate in managed care plans.

Even though HIPAA and state laws provide that small-employer health insurance coverage must be issued regardless of the health status of employees and dependents, many states allow rates to vary for the group based on overall health status. To determine the health status of the group, each employee is required to complete an individual questionnaire with detailed health information on the employee and all family members to be covered. The underwriter normally uses only information obtained from the application, but sometimes the underwriter will request additional information from an applicant's physician or may telephone the applicant to clarify an item on the application. If an underwriter is unable to obtain information necessary to accurately determine the risk of a particular applicant, he or she will underwrite more conservatively, meaning that the assumption relative to the missing information will be negative rather than positive.

For example, if an underwriter sees that a person has a history of high blood pressure that appears to be normal with medication and has a weight within normal limits, but is unable to determine whether or not the individual smokes and has a normal cholesterol level, the underwriter will assume that the missing information is negative.

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[1] When we refer to group size, we are referring to the number of employees, not the total number of covered persons, which would include dependents.

[2] Availability in the individual market impacts the small-employer market dramatically. People who have difficulty qualifying for individual coverage in the individual market often try to find ways to make themselves eligible as a group, sometimes by enrolling family members as employees who may not be

Each employee application is considered individually, usually using a point system, and the overall negative points determine whether the group will be issued at the rates quoted or with a rate-up. On a very small group, one applicant with a health history that would have resulted in a "decline" prior to guaranteed-issue laws will result in a maximum rate-up for the group in most circumstances. It is very important, therefore, that each employee's application be as complete as possible in order to ensure that initial rates are accurate.

The most common type of state rating law allows groups to be rated 25% above or 25% below an "indexed" rate. The indexed rate is determined by averaging the lowest and highest possible rates. Most insurance carriers offer the lowest legal rate on their initial quotes, or 25% below the indexed rate, in states that employ this maximum. If a group's health status is such that it would be rated at the maximum level, this means that its final rate could be 67% higher than the rate initially quote. Most states that have this type of rating system also have a limit on rate increases due to the health status of the group, which is helpful in stabilizing rates over time. Even with these initial rate fluctuations for a new group, small-employer rates in these states tend to be lower than in states where health status rating is not allowed. A group that is rated correctly up front is much less likely to have a very large increase at renewal and, in order to rate the group correctly, the correct information on the initial application is essential. A chart showing the rating laws in each state is attached.

Midsize Employers of 50-300 Employees

This market is considered to be the "medium-size" market. Most employers in this category purchase fully insured health insurance or HMO policies that are regulated by state departments of insurance or another state regulatory body. Many employers of this size offer PPO plans, and a large number offer more than one plan choice for employees.

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actually eligible, for example. This gaming of the system is a type of adverse selection and causes rates to increase for small-employer plans.

It is quite common for an employer to "shop" its health insurance plan every year to be sure it is getting the best value for its dollar. This is normally done with the assistance of an insurance broker.

In order to obtain bids for coverage, employers that have a current health plan or plans are required to provide three years of claims experience to the carriers from which they are soliciting a bid for coverage. Claims experience is a listing of paid premiums vs. paid claims, and includes a calculation for anticipated claims that have not yet been received by the in-force carrier.[3] The claims experience will typically include a list of large claims by amount and the diagnosis associated with the claim. If this is not included with the claims experience, the bidding insurance carrier will request the large claim information. The bidding carrier will also ask about any known serious illnesses to the best of the employer's knowledge, such as cancer, heart problems, AIDS and the prognosis of each, to the best of the employer's knowledge. Names of the employees with these conditions are not requested, but gender and age for the employee or dependent with the condition may be requested, as it may better enable the underwriter to assess the risk.

Sometimes other questions are asked as well. For example, if a person has had recent heart surgery, questions about current blood pressure, weight, smoking status and cholesterol level might be asked. Supplying this information can have a very positive impact on the rates the employer pays for coverage. For example, if an employee who had a large claim is now deceased or is no longer employed, or if the large claim was due to an accident from which the employee has completely recovered, the amount of the large claim is adjusted out of the overall claims experience. If a person had bypass surgery early in the previous plan year, has recovered well and now has normal lab work and blood pressure readings, the chances of another large claim occurring soon are very low, and the underwriter will take that into consideration in setting the plan rates.

[3] Claims that have been incurred but not reported are referred to as IBNR claims.

If the employer is not able to supply large claim and serious illness information, the insurance carrier may either underwrite more conservatively[4] to be sure it covers its bases on the risk assessment or, in some instances, may decline to write coverage on the group. Groups over 50 lives are **not** guaranteed issue. Even though a larger group has more employees over which to spread risk, a group of 50-300 is not considered large enough to spread all possible risks it may contain, and it is necessary to identify particularly high risks in order to establish rates that are adequate to sustain the cost of claims and administration. If the employer is unaware of a serious condition, the health plan will not come back mid-year and penalize the employer for not reporting the condition during the bid process, but an adjustment based on the actual risk will be made at the plan's renewal.

In addition to the claims experience, a list of employees, including gender, date of birth and the type of family members to be covered,[5] is required to calculate an average age for the group and male and female content. Age has an obvious impact on the level of claims because older individuals statistically have higher medical expenses. Females tend to incur higher costs than males until about age 50, and that is the reason for the calculation on gender.

A group of 300 is considered to be 100% credible for its claims experience by most insurance companies. This means that if an employer has three years of available claims experience, an accurate rate can be calculated even without information on age or gender of the employees, just based on the group's past experience. Statistically, most groups follow a fairly predictable three-year pattern if they are large enough.

Of the three years of claims experience, the most weight is given to the most recent year. In addition, insurance carriers have a "book rate" based on their experience with other groups of employees of similar age, gender and industry. The book rate is used for newer groups that haven't had previous coverage and for groups that are a little smaller and not fully credible with their own claims experience. For example, a group of 200 might be

[4] When underwriters underwrite more conservatively, they put a "load" on the rates to account for an expected margin of error.
[5] Spouse only, children only or the entire family

considered 75% credible for its claims experience. Therefore, in calculating the rate, claims experience would be given 75% weight and the book rate would be given 25%. A group of 150 might be considered 50% credible and a group of 100 might be 25% credible. A group of 50 would receive a 100% book rate, modified by any known serious health conditions. This can vary slightly from carrier to carrier, but the general process is the same.

Rate Stability

A number of things can impact a group's rates from year to year. A group may have a large number of maternity cases in a single year, or one or more persons may have large claims that cause the group's claims experience to be abnormally high. New state or federal laws that require payment for specific items and services are not without cost. This cost adds to the total cost of claims paid under the plan, which in turn causes premiums to increase. The cost of prescription drugs is increasing for all employers, as is the cost of medical care in general. Even if nothing unusual happens in a group in a given year, these increasing costs may cause a group's claims experience to go up, and its rates to be increased at the plan's renewal. This is why it is so critical that the rates be as accurate as possible from the start. A plan with rates that are set too low initially will simply recoup its losses at renewal with a very large increase. These large fluctuations in premium are very unsettling for employers and employees, and can result in some employees dropping coverage as they become unable to pay their share of premiums.

Self-Insured Plans

Self-funded or self-insured plans are plans in which the employer takes the risk for the cost of health claims, rather than purchasing a plan from an insurance company. The employer often buys stop-loss coverage to protect against excessive losses, but retains financial responsibility for the plan.

Underwriting in self-funded plans works just like it does for fully insured plans in this market, primarily because of the stop-loss insurance. Although most employers in this

category are fully insured, a large number are partially self-funded and are subject to federal rather than state regulation. In a self-funded plan, an employer usually selects an insurance carrier or third-party administrator to administer claims, a PPO or HMO network of physicians, hospitals and other providers for preferred-provider benefits, a pharmacy benefit manager to manage prescription drug benefits, and a utilization review organization if this service is not performed by the preferred-provider network. Each of these services is normally purchased on a separate monthly-fee-per-employee basis, although the cost of some services may be combined if purchased from the same vendor.

The self-funded employer also normally purchases what is called specific stop-loss insurance to protect against large claims of any one individual covered by the plan, and aggregate stop-loss insurance to protect against excessive utilization by the group as a whole. Once an individual's or group's claims reaches the stop-loss level, the reinsurance carrier is responsible for the claims for the individual or the group, depending on the type of loss, for the balance of the contract year. In order for an employer to know how much stop-loss coverage is appropriate for its group, the same information asked of fully insured cases relating to overall claims experience, large claims and serious illnesses is required. Since stop-loss levels are established based on expected claims, it is very important to be as accurate as possible in anticipating future claims. Complete information during the underwriting process is extremely important or an employer may be forced to set stop-loss levels too high, resulting in inadequate protection in the event of a year of high claims.

Groups of 300 or More Employees

Larger-group underwriting works in a manner similar to that described for midsize employer groups. The differences are a matter of degree. Claims experience is required during the underwriting process but, for a larger group, a claim may not be considered large until it reaches $25,000, $30,000 or even larger.

For this reason, the number of claims that must be reported in the large claim listing may be fewer. Information on serious illnesses will be requested, but detailed information on prognosis is less important. The reason fewer questions are asked is that the larger the group becomes, the more credible its past claims experience is, even with some large claims thrown into the mix. Even large employers, however, have difficulty anticipating and budgeting for cost increases due to new technology and the cost of prescription drugs.

The other thing that changes is that the larger the group is, the more likely it is to be partially self-funded and, if really large, fully self-funded. Stop-loss coverage is usually purchased, but with a higher trigger point for claims as the group becomes larger and better able to handle cash flow fluctuations. Third-party administrators, brokers and consultants use formulas to help employers determine the level of stop-loss coverage that is appropriate based on expected claims, group size and the employer's level of risk tolerance.

Large employers also have greater ability, due to volume purchasing, to offer variety to employees, including multiple plan options. Large employers are also increasing their use of disease-management programs, wellness programs and options for alternative medicine.

One thing that should be noted is that not all employers that self-fund use administrators and insurance carriers. Although it is not very common, there are employers who self-administer their benefits plans. Not all of these employers are "jumbo" employers, and some are in the 50-300 size category. Self-administration is done to save money, and many of the employers that employ this method would not be able to afford to offer a plan if they didn't administer it themselves. The smaller employers that self-administer usually offer decent coverage without complicated provisions. These employers take great care to pay claims accurately, and actually understand the stop-loss provisions of their reinsurance contracts very well. The reinsurance coverage they purchase requires all of the same information gathering required under other arrangements, although it is

sometimes more difficult for them to obtain reinsurance without the "official" prior claims documentation provided by a third-party claims administrator or insurance carrier.

Additional Information about Rates on Health Plans

Rates are also obviously impacted by plan design and type. Rates for PPO plans are usually, but not always, higher than HMOs, partly because the way providers are paid impacts the ultimate claims cost. PPO plans pay preferred providers based on a discounted fee for service or, in some cases, on a previously agreed to per-diem rate for things like hospital stays. Sometimes "case" rates are paid for maternity or similar types of common expenses. A case rate is a lump sum paid for a certain types of expenses. For example, an uncomplicated vaginal delivery might have a case rate of $1,000. Out-of-network providers are paid based on a percentile of the usual and customary (UCR) cost of a service in the ZIP code of the provider. Some plans pay out-of-network providers based on the 80th percentile of UCR, some on the 70th percentile, and some on the 90th percentile. The percentile used is important because on out-of-network claims, the insured is responsible for all charges the insurance plan doesn't pay for, and because it impacts the dollar amount of total claims paid.

Example: Employee is covered by a plan that pays for services at 90% in network and 70% out of network. Out-of-network charges are paid on the 90th percentile. Employee has surgery by an out-of-network physician who charges $1,000. Ninety percent of physicians in the area charge $900 or less for the procedure, so the physician the employee selected is above the 90% percentile of usual and customary charges by $100. Here is how the claim is paid at both the 80th and 90th percentiles:

	At 90th Percentile	At 80th Percentile
Surgery	$1,000	$1,000
Minus amount over Usual & Customary Charges	$ 100	$ 150
Covered fee	$ 900	$ 850

Insurance pays 70%	$ 630	$ 595
Employee pays 30% plus amount over UCR	$ 370	$ 405

If the insured uses an in-network PPO provider, then the insured would not be responsible for charges in excess of the contract rate. Example:

	Charges
Regular rate for the surgery	$1,000
Contract rate for the surgery	$ 650
Insurance pays 90%	$ 585
Employee pays 10% of contract rate	$ 65

As you can see, because of the PPO discount, both the plan and the employee pay less with the PPO provider, even though the plan is paying at 90%. This means claims payments will be less and premiums lower if most employees use preferred providers. It also is an incentive for plans to develop full networks of providers. In this instance, if the plan did not have an adequate network and had to pay the full undiscounted rate to the surgeon at 90%, the plan would have paid $900 for a service that should have cost it $585.[6]

Premiums on PPO plans are also impacted by the ability of the plan to negotiate discounted fees with preferred providers. In rural areas, it is often difficult to negotiate a discounted fee with a physician who may be the only specialist of that type in town, and many physicians in rural areas don't negotiate at all. In those situations, there may be

[6] One of the reasons rural areas have fewer PPO and other managed care plan options is that PPOs and HMOs frequently experience difficulty in getting physicians in rural areas to participate. This results in the problem described above, where the plan is forced to pay for a service at the full undiscounted rate at the highest applicable percentage, while the employee's cost-sharing is not allowed to be more than it would have been with an in-network provider, because of rules on network adequacy. Network-adequacy rules require plans to include providers in each specialty that might be required by people insured under the plan, as well as provide for adequate facilities for lab, x-ray and hospital care. In this case, a plan may decide it's not economically feasible to offer coverage in the area, or may attempt to control costs with a "hospital

few PPOs available and, for those that are available, it is much more likely that out-of-network claims will be paid at a lower percentile of UCR and that the percentage payable will be less. If you go back to the example above, you will note that the out-of-network claim paid at the 80th percentile resulted in a payment by the plan similar to the payment made to the PPO provider. The difference in this situation is that for out-of-network claims, the insured takes on all of the responsibility for the amount not paid by the carrier while, with preferred providers, the provider absorbs the cost.

In addition, even though the flexibility of a PPO is attractive, there are few barriers to utilization and, as a result, costs may be higher than they would be under an HMO. All rates are based on claims, whether it is the group's own claims experience or a book rate. Therefore, anything that increases the ultimate cost of claims paid out will impact the rate paid. This includes the cost of prescription drugs; for this reason, many employers that want to retain as high a level of benefits as possible for non-pharmaceutical benefits are requiring increasingly larger copays for drugs, especially those not on the formulary.

HMOs pay providers in a variety of ways. Some actually pay physicians the same way PPOs do, based on a discounted fee for service. This is especially common when an HMO enters a new area and doesn't yet have a significant market share. But, more commonly, the HMO pays a primary care physician a fixed rate, called a capitated rate, per member per month, regardless of the number of times a person may or may not have seen the physician that month. Some specialists are capitated the same way, and others are paid a discounted fee for service. Certain specialties are very likely to be capitated, such as anesthesia, pathology and radiology. Hospitals are usually paid on a per-diem basis, although they may be capitated or paid a case rate for some types of admissions.

HMOs usually require a referral from the primary care physician for a patient to see a specialist, and only cover care from network providers. The idea of referrals is to ensure that only patients who actually require specialty care are seen by plan specialists.

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only" PPO or an indemnity plan where it can have some control over reimbursements by lowering the percentile it uses for usual and customary charges.

Because primary care physicians are capitated, the cost of non-hospital care is more predictable and is usually lower than under a PPO where costs are more impacted by the rate of utilization. Most services require authorization from the primary care physician, and this more tightly managed care results in greater cost efficiencies.

In spite of this management of care, a sick person will result in high costs regardless of the type of plan. How high the costs are will vary by degree with the plan type. HMO rates are typically based on the "community" of members in their pool; however, they are permitted to make adjustments based on the demographics of the actual group to be insured. Again, it is essential that the bidding HMO have accurate information on the actual group to be insured in order to establish adequate initial rates.

One other type of common option is a point of service (POS) plan. This type of plan option is often confused with a PPO because they look similar on the surface. In reality, a POS plan is simply an HMO with an option to use out-of-network providers. Usually the out-of-network option is significantly less attractive than an out-of-network option on a PPO plan, and the in-network portion of the plan is an HMO. This means that in the network, all HMO rules must be followed, including rules on referrals for in-network specialty care. While not quite as flexible as a PPO plan, a POS plan offers a good value for the dollar, especially if HMO providers will be used most of the time, while still allowing a safety net for people who want to retain the option of using non-network providers.

Addendum B

A Comparison of Individual Market Health Insurance Costs and Individual Health Insurance Market Regulatory Factors for Low-Income Families Across the United States (Rates as of June 2005)

In this analysis, the National Association of Health Underwriters (NAHU) compares how much a health insurance policy purchased by a low-income American family through the individual health insurance market in each state would cost, as well as what type of plan benefits would be available to them. We assumed this was a family made up of a single mother, age 35, and two healthy daughters, ages seven and nine. When obtaining these rates, we assumed that each of these fictional individuals were healthy, non-smokers with creditable coverage who live in the same ZIP codes and counties as the capitals in each of these states. We also assumed that coverage would begin on June 1, 2005.

For each state, NAHU sought out PPO family coverage that cost approximately $250 per month, or approximately $3000 per year. In most states there was coverage in this price range, and less expensive policies were also available; however, in some cases similar coverage could not be obtained in that price range so the least expensive equivalent policy information is listed. In addition to the rates and policy benefits listed, we also provide a summary of the individual health insurance market regulatory climate in each state, which can have a substantial impact on health insurance rates and the availability of coverage.

State	Individual Market Health Insurance Options for Subject Family					Regulatory and Market Factors That May Impact Individual Market Health Insurance Pricing and Availability
	Plan Type	Monthly Premium	Annual In-Network Deductible (Individual /Family)	Coinsurance Rate	Additional Policy Benefits	
Alabama 36130	PPO	$245.34	$1500/$3000	100% coverage after the deductible.	Office visits, hospitalization and RX are subject to deductible. Additional $100 ER co-pay, and $50 outpatient co-pay and $3000 lifetime maximum for mental health services. Annual $1500/$3000 out-of-pocket maximum.	No rate caps and medical underwriting allowed. High-risk pool to serve HIPAA-eligible population. Allows for elimination riders. 60-month look-back and 24-month exclusionary period limit for preexisting conditions. State regulation of managed care entities makes it extremely difficult for carriers to offer individual market PPO products.

State	Individual Market Health Insurance Options for Subject Family					Regulatory and Market Factors That May Impact Individual Market Health Insurance Pricing and Availability
	Plan Type	Monthly Premium	Annual In-Network Deductible (Individual /Family)	Coinsurance Rate	Additional Policy Benefits	
Alaska 9 9 8 1 1	Managed Indemnity	$289.30	$5000/$15000	100% coverage after the deductible.	Non-preventive office visits and hospitalization are subject to deductible and coinsurance. Additional $50 ER deductible (waived if admitted). Mental health up to $1,000 per insured per calendar year, limited to 25 visits per year, charges paid at 50% including prescriptions, $40 maximum benefit per day, $10,000 lifetime maximum inpatient and out patient combined. RX discount card, average 15% discount. Annual $5000/$15000 out-of-pocket maximum.	No rate caps and medical underwriting allowed. High-risk pool to serve the state's medically uninsurable and HIPAA-eligible populations. Elimination riders allowed. Geographical considerations may impact competition and prices.
Arizona 85007	PPO	$236.12	$1500/$3000	100% coverage after the deductible.	Office visits, hospitalization and RX are subject to deductible and coinsurance. Additional $100 ER co-pay, and $50 outpatient co-pay and $3000 lifetime maximum for mental health services. $1500/$3000 annual out-of-pocket maximum.	No rate caps and medical underwriting allowed. No mechanism to serve the state's medically uninsurable population. Individual market serves as the GI option for HIPAA-eligible population. Elimination riders allowed, except for HIPAA-eligible individuals. Credit for prior coverage not required, except for HIPAA-eligibles. Preexisting conditions may not be considered for HIPAA-eligibles. No look-back or exclusionary period limit for preexisting conditions for other individual policies. The Healthcare Group of Arizona Purchasing Pool must GI coverage to groups-of-one.
Arkansas 72201	PPO	$225.72	$1500/$3000	100% coverage after the deductible.	Office visits, hospitalization and RX are subject to deductible and coinsurance. Additional $100 ER co-pay, and $50 outpatient co-pay and $3000 lifetime maximum for mental health services. $1500/$3000 annual out-of-pocket maximum.	No rate caps and medical underwriting allowed. High-risk pool to serve the state's medically uninsurable and HIPAA-eligible populations. 60-month look-back period limit on preexisting conditions. Elimination riders allowed.

State	Individual Market Health Insurance Options for Subject Family					Regulatory and Market Factors That May Impact Individual Market Health Insurance Pricing and Availability
	Plan Type	Monthly Premium	Annual In-Network Deductible (Individual /Family)	Coinsurance Rate	Additional Policy Benefits	
California 95814	PPO	$239.00	$2500/$5000	70% coverage after the deductible.	$30 office visit co-pay. Separate $100 deductible for RX with $15/35/50 30-day pharmacy co-pay and $30/70/100 90-day mail-order co-pay. ER visits, mental health and hospitalization are subject to additional co-pays following the deductible. $4500/$9000 annual family out-pf-pocket maximum.	No rate caps and medical underwriting allowed. High-risk pool to serve the state's medically uninsurable population. All carriers must GI their two most popular products to the HIPAA-eligible population and to people who have exceeded two years in the risk-pool. Elimination riders not allowed. Credit for prior coverage required. 12-month look-back and exclusionary period limit for preexisting conditions for 1-2 lives covered by an individual policy. 6-month look-back and exclusionary period limit for 3 or more lives covered by an individual policy.
Colorado 80203	PPO	$262.10	$2000 (individual only)	80% in-network coverage after the deductible.	$30 office visit co-pay. $15/40/60 RX co-pay. 50% mental health coinsurance rate. $3000 annual per-member out-of-pocket maximum.	No rate caps and medical underwriting allowed. High-risk pool to serve the state's medically uninsurable and HIPAA-eligible populations. Elimination riders allowed for medical conditions. Credit for prior coverage required. 12-month look-back and exclusionary period limit for preexisting conditions. Carriers must GI basic and standard small-group coverage during an annual open enrollment window to groups-of-one with involuntary loss of coverage only.
Connecticut 06106	PPO	$238.57	$1500/$3000	80% coverage after the deductible.	Office visits, hospitalization and RX are subject to deductible and coinsurance. Additional $100 ER co-pay, and $50 outpatient co-pay and $3000 lifetime maximum for mental health services. $1000 individual annual out-of-pocket maximum.	No rate caps and medical underwriting allowed. High-risk pool to serve the state's medically uninsurable and HIPAA-eligible populations. Elimination riders allowed. Credit for prior coverage required. 12-month look-back and exclusionary period limit for preexisting conditions. Carriers must GI standardized small-group coverage to groups-of-one.

State	Individual Market Health Insurance Options for Subject Family					Regulatory and Market Factors That May Impact Individual Market Health Insurance Pricing and Availability
	Plan Type	Monthly Premium	Annual In-Network Deductible (Individual /Family)	Coinsurance Rate	Additional Policy Benefits	
Delaware 19901	PPO	$254.16	$1500/$3000	100% coverage after the deductible.	Office visits, hospitalization and RX are subject to deductible and coinsurance. Additional $100 ER co-pay, and $50 outpatient co-pay and $3000 lifetime maximum for mental health services. $1500/$3000 annual out-of-pocket maximum.	No rate caps and medical underwriting allowed. No mechanism to serve the state's medically uninsurable population. Individual market serves as the GI option for the HIPAA-eligible population. Elimination riders allowed except for the HIPAA-eligible population. Credit for prior coverage only required of the HIPAA-eligible population. Carriers must GI small-group coverage to groups-of-one.
District of Columbia 20004	PPO	$251.00	$2500/$5000	80% coverage after the deductible.	$30 primary care office visit co-pay . $40 specialist office visit co-pay. $15/25/40 RX co-pay with $5000 annual maximum and $500 calendar year deductible for non-generic drugs. ER visits subject to $100 co-pay if not admitted. Mental health office visits subject to 75% coinsurance for the first 40 visits and 60% thereafter. $5000/$10000 annual out-of-pocket maximum.	No rate caps and medical underwriting allowed. Limited GI coverage during an annual open enrollment with a 2-month waiting period available through Carefirst BCBS for the medically uninsurable population. Individual market serves as the GI option for the HIPAA-eligible population. Elimination riders allowed except for the HIPAA-eligible population and the BCBS GI product. 12-month exclusionary period limit for preexisting conditions for HMOs. 10-month exclusionary period limit for preexisting conditions for BCBS GI product. Credit for prior coverage only required of the HIPAA-eligible population.

State	Individual Market Health Insurance Options for Subject Family					Regulatory and Market Factors That May Impact Individual Market Health Insurance Pricing and Availability
	Plan Type	Monthly Premium	Annual In-Network Deductible (Individual /Family)	Coinsurance Rate	Additional Policy Benefits	
Florida 32399	PPO	$239.16	$1500/$3000	80% coverage after the deductible.	Office visits, RX, hospitalization and ER subject to the deductible. $500 outpatient/$2500 inpatient annual maximum for mental health and 50% coinsurance. $2000/$4000 annual out-of-pocket maximum.	No rate caps and medical underwriting allowed. Legislation passed in 2004 to create a new risk pool for the medically uninsurable population, however at this time it is not funded. The current risk-pool for medically uninsurable population is currently closed to new applicants. Individual market serves as the GI option for the HIPAA-eligible population. Elimination riders permitted, except for HIPAA-eligible population. 24-month look-back and exclusionary period limit for preexisting conditions. Preexisting conditions may not be considered for HIPAA-eligible population. Credit for prior coverage required. Carriers must GI certain small-group coverage to groups-of-one during annual open enrollment period.
Georgia 30303	PPO	$237.80	$2500/$5000	80% coverage after the deductible.	Office visits, hospitalization and ER subject to the deductible. $500 RX deductible and then $10/30/50/25% co-pay. $500 outpatient/$2500 inpatient annual maximum for mental health and 50% coinsurance. $2000 individual annual out-of-pocket maximum.	No rate caps and medical underwriting allowed. 24-month exclusionary period limit for preexisting conditions. No mechanism to serve the state's medically uninsurable population. Carriers must provide GI coverage to the HIPAA-eligible population on an assignment basis. Elimination riders permitted except for the HIPAA-eligible population under certain circumstances. Credit for prior coverage not required except for the HIPAA-eligible population under certain circumstances.

State	Individual Market Health Insurance Options for Subject Family					Regulatory and Market Factors That May Impact Individual Market Health Insurance Pricing and Availability
	Plan Type	Monthly Premium	Annual In-Network Deductible (Individual /Family)	Coinsurance Rate	Additional Policy Benefits	
Hawaii 96813	HMO	$294.50	None	70% coverage.	$15 office visit co-pay, $50 ER co-pay and $35 ER physician co-pay, hospitalization subject to coinsurance, and maternity subject to 90% coinsurance. $7500/$22000 annual out of-pocket maximum.	No rate caps and medical underwriting allowed. No mechanism to serve the state's medically uninsurable population that does not have access to the group market. Individual market serves as the GI option for the HIPAA-eligible population. 36-month exclusionary period limit for preexisting conditions. Preexisting conditions may not be considered for HIPAA-eligible population. Elimination riders permitted, except for the HIPAA eligible population. Credit for prior coverage not required, except for the HIPAA-eligible population. State's group coverage mandate for employees that work 20 or more hours per week Geographical considerations may impact competition and prices.
Idaho 83720	PPO	$245.02	$3000 Individual (deductibles waived for all other insureds after three family members meet their deductible)	80% coverage after the deductible.	Hospitalization, ER, RX and office visits subject to the deductible and coinsurance. Separate $5000 maternity deductible. Separate coinsurance and benefit limits for mental health services. $5500 annual out-of-pocket maximum.	Rates are subject to bands of plus or minus 50 percent of the base individual market rate for experience, health status and duration, with variances also allowed for age and gender. Carriers must GI at least three products (basic, standard and catastrophic) to all individual market consumers with 12 months of creditable coverage. State individual market high-risk reinsurance pool to provide the medically uninsurable population with lower cost GI coverage. 6-month look-back and 12-month exclusionary period limit for preexisting conditions. Preexisting conditions may not be considered for standardized policies. Credit for prior coverage required. Elimination riders not permitted.

State	Individual Market Health Insurance Options for Subject Family					Regulatory and Market Factors That May Impact Individual Market Health Insurance Pricing and Availability
	Plan Type	Monthly Premium	Annual In-Network Deductible (Individual /Family)	Coinsurance Rate	Additional Policy Benefits	
Illinois 62706	PPO	$209.96	$1000/$3000	80% coverage after the deductible.	Office visits and hospitalization are subject to deductible and coinsurance. Additional $75 ER co-pay (waived if admitted), and separate $500 RX deductible with $10/30/50/25% co-pays. $2500 annual maximum for mental health services with 50% coinsurance. Annual out-of-pocket maximum per individual is $2000 in addition to deductibles.	No rate caps and medical underwriting allowed. High-risk pool serves the state medically uninsurable and HIPAA-eligible populations. Elimination riders allowed except for HIPAA population. Credit for prior coverage not required except for HIPAA population. 12-month look back period during first two years of coverage, and if the condition is determined to be preexisting a 24-month exclusionary period is allowed, as is a 12-month exclusionary period for symptoms.
Indiana 46204	PPO	$244.01	$2500/$5000	100% coverage after the deductible.	Office visits, hospitalization and RX are subject to deductible and coinsurance. Additional $100 ER co-pay, and $50 outpatient co-pay and $3000 lifetime maximum for mental health services. Annual out-of-pocket maximum is $2500/$5000.	No rate caps and medical underwriting allowed. High-risk pool serves the state medically uninsurable and HIPAA-eligible populations. 12-month look-back and 24-month exclusionary period limit for preexisting conditions. Elimination riders not permitted. Credit for prior coverage required only in the small group market.

State	Individual Market Health Insurance Options for Subject Family					Regulatory and Market Factors That May Impact Individual Market Health Insurance Pricing and Availability
	Plan Type	Monthly Premium	Annual In-Network Deductible (Individual /Family)	Coinsurance Rate	Additional Policy Benefits	
Iowa 50319	PPO	$204.06	$1500/$3000	100% coverage after the deductible.	Office visits, hospitalization and RX are subject to deductible and coinsurance. Additional $100 ER co-pay, and $50 outpatient co-pay and $3000 lifetime maximum for mental health services. Annual out-of-pocket maximum is $1500/$3000.	Carriers are subject to rating restrictions based on the pricing for of their different blocks of business. The rate differential between the two policy forms must be no more than 2.028 to 1 at each age, i.e., the composite effect of 30%, and 20%. Subsequent rate changes must be within 15% of each other. Carriers must GI standardized policies for residents with 12 months of creditable coverage that meet other specified criteria. High-risk pool serves the state medically uninsurable and HIPAA-eligible populations. Elimination riders permitted. Credit for prior coverage required for HIPAA-eligibles and standardized policies. Preexisting conditions may not be considered for HIPAA-eligibles. 12-month look-back and exclusionary period limit on preexisting health conditions for standardized GI policies. 60-month look-back and 12-month exclusionary period limit on preexisting health conditions for all other individual market policies.
Kansas 66612	PPO	$238.08	$2500/$5000	80% coverage after the deductible.	Office visits, mental health and hospitalization are subject to deductible and coinsurance. Additional $75 ER co-pay (waived if admitted), and separate $500 RX deductible with $10/30/50/25% co-pays. Varying coinsurance rates for mental health outpatient visits and 30-day limit for mental health/chemical dependency inpatient care. Annual out-of-pocket maximum per individual is $2000 in addition to deductibles.	No rate caps and medical underwriting allowed. High-risk pool serves the state medically uninsurable and HIPAA-eligible populations. Elimination riders allowed. Credit for prior coverage not required. 12-month look-back and 24-month exclusionary period limit for preexisting conditions.

State	Individual Market Health Insurance Options for Subject Family					Regulatory and Market Factors That May Impact Individual Market Health Insurance Pricing and Availability
	Plan Type	Monthly Premium	Annual In-Network Deductible (Individual /Family)	Coinsurance Rate	Additional Policy Benefits	
Kentucky 40601 (Franklin County)	PPO	$220.90	$1000/$2000	80% coverage after the deductible.	Office visits, hospitalization, mental health and ER visits are subject to the deductible and coinsurance. $15 co-pay for generic/formulary RX, non-generic/formulary not covered. $3000/$6000 annual out-of-pocket limit.	Rates are subject to bands of plus or minus 35 percent of the base individual market rate. High-risk pool serves the state medically uninsurable and HIPAA-eligible populations. Elimination riders not permitted. Credit for prior coverage required. 6-month look-back and 12-month exclusionary period limit for preexisting conditions.
Louisiana 70804	PPO	$238.10	$5000/$15000	100% coverage after the deductible.	$10 office visit co-pay for non-preventive care. RX discount card. Hospitalization subject to deductible, and ER subject to $50 additional deductible (waived if admitted). Annual mental health benefit limits of $1000/25 visits out-patient/$2500 inpatient, and coverage is subject to coinsurance. $5000/$15000 annual out-of-pocket maximum.	No rate caps and medical underwriting allowed. (Statutory rate bands are not enforced in Louisiana's individual health insurance market.) High-risk pool serves the state medically uninsurable and a separate pool serves the HIPAA-eligible populations. Elimination riders allowed. Credit for prior coverage required. 12-month look-back and exclusionary period limit for preexisting conditions.

State	Individual Market Health Insurance Options for Subject Family					Regulatory and Market Factors That May Impact Individual Market Health Insurance Pricing and Availability
	Plan Type	Monthly Premium	Annual In-Network Deductible (Individual /Family)	Coinsurance Rate	Additional Policy Benefits	
Maine 04333	PPO	$267.98	$5000/$10000	100% coverage after the deductible.	Office visits, RX coverage, ER visits and hospitalization all subject to the deductible. Preventive care and well-baby care covered outside of the deductible, with benefit maximums	All major medical products must be offered on a GI basis. Modified community rating with adjustments of plus or minus 20 percent of the community rate only allowed for age, occupation, and geography. A separate adjustment can be made for smoker status. Individual market serves as the GI option for HIPAA-eligible population. Elimination riders not permitted. Credit for prior coverage required.
Maryland 21401	PPO	$237.90	$1500/$3000	100% coverage after the deductible.	Office visits, hospitalization and RX are subject to deductible and coinsurance. Additional $100 ER co-pay, and $50 outpatient co-pay and $3000 lifetime maximum for mental health services. Annual out-of-pocket maximum is $1500/$3000.	No rate caps and medical underwriting allowed, except for a 200% of the base rate cap for HIPAA eligibles. High-risk pool serves the state medically uninsurable and HIPAA-eligible populations. Elimination riders allowed except for HIPAA-eligibles. Credit for prior coverage required for HIPAA eligibles. 4-month look-back and 24-month exclusionary period limit for preexisting conditions. Preexisting conditions may not be considered for HIPAA-eligibles and HMO plans. Carriers must GI coverage standardized plan to self-employed individuals during annual open enrollment period.

State	Individual Market Health Insurance Options for Subject Family					Regulatory and Market Factors That May Impact Individual Market Health Insurance Pricing and Availability
	Plan Type	Monthly Premium	Annual In-Network Deductible (Individual /Family)	Coinsurance Rate	Additional Policy Benefits	
Massachusetts	PPO	$377.49	$5000/$10000	100% coverage after deductible.	Office visits, ER visits, hospitalization, maternity and mental health services subject to the deductible. RX discount card available. $5000/$10000 annual out-of-pocket maximum.	Carriers must GI at least three individual market products to all consumers. Modified community rated basis, with adjustments limited to age, geography and benefit level on a 2:1 basis. Individual market serves as the GI option for HIPAA-eligible population. Elimination riders not permitted. Credit for prior coverage required. 6-month look-back and exclusionary period limit for preexisting conditions. Carriers must GI coverage to groups-of-one.
Michigan 48909	PPO	$221.55	$1500/$3000	100% coverage after the deductible.	Office visits, hospitalization and RX are subject to deductible and coinsurance. Additional $100 ER co-pay, and $50 outpatient co-pay and $3000 lifetime maximum for mental health services. Annual out-of-pocket maximum is $1500/$3000.	No rate caps and medical underwriting allowed, except for BCBS of Michigan and HMOs. BCBS of Michigan must GI products to all residents and groups-of-one. BCBS of Michigan serves as the GI option for HIPAA-eligibles. HMOs must GI all products during an annual open-enrollment period. Elimination riders not permitted. Credit for prior coverage not required. 6-month look-back and a 12-month exclusionary period limit on preexisting health conditions. 6-month look-back and exclusionary period limit preexisting health conditions for BCBS and HMOs.

State	Individual Market Health Insurance Options for Subject Family					Regulatory and Market Factors That May Impact Individual Market Health Insurance Pricing and Availability
	Plan Type	Monthly Premium	Annual In-Network Deductible (Individual /Family)	Coinsurance Rate	Additional Policy Benefits	
Minnesota 55155	PPO	$234.83	$1500 (individual only with limit of three deductibles per family per year)	80% coverage after the deductible.	Office visits, hospitalization, mental health, maternity and ER are subject to the deductible, with an 18-month initial exclusion for maternity. No deductible for pre-natal care. Separate $500 RX deductible. $2500 individual annual out-of-pocket maximum.	Rates are subject to bands of plus or minus 25 percent of the base individual market rate for health status, plus or minus 50 percent for age and plus or minus 20 percent for geography. High-risk pool serves the state medically uninsurable and HIPAA-eligible populations. High-risk pool has a 3-month look-back and a 6-month exclusionary period limit on preexisting health conditions for people without creditable coverage. Elimination riders not permitted for policies issued after 1993. Credit for prior coverage required. No exclusionary period allowed for preexisting health conditions for people with creditable coverage.
Mississippi 39201	PPO	$217.14	$2500/$5000	100% coverage after the deductible.	Office visits, hospitalization and RX are subject to deductible and coinsurance. Additional $100 ER co-pay, and $50 outpatient co-pay and $3000 lifetime maximum for mental health services. Annual out-of-pocket maximum is $2500/$5000.	No rate caps and medical underwriting allowed. High-risk pool serves the state medically uninsurable and HIPAA-eligible populations. Elimination riders allowed. Credit for prior coverage not required. 12-month look-back and exclusionary period limit for preexisting conditions.

State	Individual Market Health Insurance Options for Subject Family					Regulatory and Market Factors That May Impact Individual Market Health Insurance Pricing and Availability
	Plan Type	Monthly Premium	Annual In-Network Deductible (Individual /Family)	Coinsurance Rate	Additional Policy Benefits	
Missouri 65101	PPO	$250.88	$2500/$5000	80% coverage after the deductible.	$25 primary care/$40 specialty care office visit co-pays up to 4 visits per year. After 4 visits are met, then 20% coinsurance after deductible. Mental Office visits, mental health and hospitalization are subject to deductible and coinsurance. Additional $75 ER co-pay (waived if admitted), and separate $500 RX deductible with $10/30/50/25% co-pays. Varying coinsurance rates for mental health outpatient visits and 30-day limit for mental health/chemical dependency inpatient care. Annual out-of-pocket maximum per individual is $2000 in addition to deductibles.	No rate caps and medical underwriting allowed. High-risk pool serves the state medically uninsurable population. All Carriers must GI basic and standard products to HIPAA-eligibles. (Missouri never enacted HIPAA enabling legislation, so there is federal enforcement of HIPAA through CMS. Elimination riders allowed except for HIPAA-eligibles.) Credit for prior coverage not required except for HIPAA-eligibles. Unlimited look-back and 24-month exclusionary period limit for preexisting conditions. Preexisting conditions may not be considered for HIPAA-eligibles.
Montana 59620	PPO	$223.68	$2000/$6000	50% coverage after the deductible.	Office visits, hospitalization and maternity are subject to deductible and coinsurance. Additional $75 ER access fee (waived if admitted), and additional $500 hospital access fee. Separate $500 RX deductible. Generic: $10 co-pay. Brand when generic not available: $25 co-pay plus 50% of remaining cost. Brand when generic available: The difference between the cost of brand vs. generic plus $25 co-pay plus 50% of remaining cost. Annual out-of-pocket maximum is $2500/$5000 plus the deductible.	No rate caps and medical underwriting allowed. High-risk pool serves the state medically uninsurable and HIPAA-eligible populations. Elimination riders allowed. Credit for prior coverage required. 36-month look-back and 12-month exclusionary period limit for preexisting conditions. Geographical considerations may impact competition and prices.
Nebraska 68509	PPO	$242.77	$1500 individual	100% coverage after the deductible.	Office visits, hospitalization and ER are subject to the deductible and coinsurance. Additional $100 ER co-pay. Mental health benefits as mandated by the state. RX discount card.	No rate caps and medical underwriting allowed. High-risk pool serves the state medically uninsurable and HIPAA-eligible populations. Elimination riders allowed. No look-back or exclusionary period limit for preexisting conditions. No look-back or exclusionary period limit for preexisting conditions.

State	Individual Market Health Insurance Options for Subject Family					Regulatory and Market Factors That May Impact Individual Market Health Insurance Pricing and Availability
	Plan Type	Monthly Premium	Annual In-Network Deductible (Individual /Family)	Coinsurance Rate	Additional Policy Benefits	
Nevada 89101	PPO	$229.00	$2000/$4000	70% coverage after the deductible.	$30 office visit co-pay up to 4 visits a year. ER, hospitalization and mental health/chemical dependency subject to deductible and coinsurance. RX coverage with separate $100 deductible and $20/30 co-pay and $100 annual limit. Mental health coverage for severe illnesses only, subject to limits and chemical dependency subject to limits. $4000/$8000 annual out-of-pocket maximum.	Rates are subject to bands of plus or minus 50 percent of the base individual market rate. Carriers must GI basic and standard plans to HIPAA-eligibles. Credit for prior coverage required. Elimination riders permitted except for HIPAA-eligibles and the basic and standard plans. Preexisting conditions may not be considered for HIPAA-eligibles. No look-back or exclusionary period limit for preexisting conditions for other individual policies.
New Hampshire 03301	PPO	$325.49	$5000	80% coverage after the deductible.	Non-preventive office visits, hospitalization and ER visits subject to deductible and coinsurance, as well as a $100 ER co-pay. $10 generic RX co-pay with $1000 annual maximum. $15000 annual out-of-pocket maximum per family.	Rates are subject to rate bands. High-risk pool serves the state medically uninsurable and HIPAA-eligible populations. Elimination riders are permitted. Credit for prior coverage is required. 3-month look-back and a 9-month exclusionary period limit on preexisting health conditions. Carriers must GI coverage to groups-of-one during bi-annual open enrollment periods.
New Jersey 08625	EPO	$420.08	None	70%	100% coverage of office visits up to $700 per year. $50 deductible for periodic health exams and OB/GYM visits, then 20% coinsurance up to $600 annual limit. $500 hospitalization co-payment and $100 ER co-payment.	Pure community rating for all products, except for the basic and essential plans which allow 3.5:1 variations for age, gender and geography. All carriers must GI five standardized products to all consumers. Elimination riders not permitted. Credit for prior coverage required. 6-month look-back and 12-month exclusionary period limit for preexisting conditions.

State	Individual Market Health Insurance Options for Subject Family					Regulatory and Market Factors That May Impact Individual Market Health Insurance Pricing and Availability
	Plan Type	Monthly Premium	Annual In-Network Deductible (Individual /Family)	Coinsurance Rate	Additional Policy Benefits	
New Mexico 87501	PPO	$228.96	$1000/$3000	80% coverage after the deductible.	Non-preventive office visits, ER and hospitalization subject to deductible. 100% coverage of preventive care up to a $400 per member annual maximum, then subject to deductible and coinsurance. RX discount card for generics. $2000/$5000 annual out-of-pocket maximum.	No rate caps and medical underwriting allowed. High-risk pool serves the state medically uninsurable and HIPAA-eligible populations. Elimination riders allowed. Credit for prior coverage required. 6-month look-back and exclusionary period limit on preexisting health conditions. The NM Health Insurance Alliance must GI coverage to HIPAA-eligibles and self-employed individuals under certain conditions.
New York 12224	PPO	$734.13	$250/$500 (out-of-network only)	100% coverage of the GHI Schedule of Allowance	Office visits not covered except for well-child visits. Separate RX deductible of $50 and $10 co-pay for generics and brand name without generic equivalent. $10 plus difference between brand and generic for brand name with generic equivalent. No RX deductible for mail order and $8/$15 co-pay for 90-day supply. Coverage of hospitalization, maternity and ER visits ($50 co-pay). Thirty days annual inpatient psychiatric care and5 days per calendar for substance abuse and detoxification. $10,000 annual out-of-pocket limit.	Coverage must be community-rated with adjustments limited to family composition and geographic regions. All carriers must GI all individual market products to all consumers. Elimination riders not permitted. Credit for prior coverage required. 6-month look-back and 12-month exclusionary period limit for preexisting conditions.

State	Individual Market Health Insurance Options for Subject Family					Regulatory and Market Factors That May Impact Individual Market Health Insurance Pricing and Availability
	Plan Type	Monthly Premium	Annual In-Network Deductible (Individual /Family)	Coinsurance Rate	Additional Policy Benefits	
North Carolina 27699-	PPO	$239.77	$5000/$15000	100% in-network coverage after the deductible.	$25 non-preventive office visit co-pay. ER and hospitalization are subject to deductible and coinsurance. Additional $50 ER deductible (waived if admitted). Mental health up to $1,000 per insured per calendar year, limited to 25 visits per year, charges paid at 50% including prescriptions, $40 maximum benefit per day, $10,000 lifetime maximum inpatient and out patient combined. RX discount card, average 15% discount. Annual $5000/$15000 out-of-pocket maximum.	No rate caps and medical underwriting allowed. No mechanism to serve the state's medically uninsurable population. Individual market serves as the GI option for HIPAA-eligible population. BCBS of NC GIs some products to all consumers. Elimination riders allowed, except for HIPAA-eligible individuals. Credit for prior coverage required. Preexisting conditions may not be considered for HIPAA-eligibles. 12-month look-back and exclusionary period limit for preexisting conditions for other individual policies. Carriers must GI basic and standard plans to groups-of-one.
North Dakota 58505	PPO	$197.76	$1600/$3200 The deductible for family coverage is integrated.	80% coverage after the deductible.	Office visits, RX, ER and hospitalization subject to deductible and coinsurance, with an additional $75 ER access fee (waived if admitted). $500 per year benefit for all wellness services. Mental health services $500 calendar year maximum $2,500 combined inpatient and outpatient, including inpatient chemical dependency with 50% coinsurance after deductible. Annual out-of-pocket maximum of $2000/$4000 plus deductible.	Rates are subject to rate bands. High-risk pool serves the state medically uninsurable and HIPAA-eligible populations. Elimination riders permitted Credit for prior coverage required. 6-month look-back and 12-month exclusionary period limit on preexisting health conditions. Geographical considerations may impact competition and prices.

State	Individual Market Health Insurance Options for Subject Family					Regulatory and Market Factors That May Impact Individual Market Health Insurance Pricing and Availability
	Plan Type	Monthly Premium	Annual In-Network Deductible (Individual /Family)	Coinsurance Rate	Additional Policy Benefits	
Ohio 43215	PPO	$233.56	$1000/$3000	80% coverage after the deductible.	Office visits, hospitalization and ER are subject to deductible and coinsurance. Additional $75 ER access fee (waived if admitted). Separate $500 RX deductible. Generic: $10 co-pay. Brand when generic not available: $25 co-pay plus 52% of remaining cost. Brand when generic available: The difference between the cost of brand vs. generic plus $25 co-pay plus 20% of remaining cost. Annual out-of-pocket maximum is $2000/$4000 plus the deductible.	No rate caps except on standardized products, and medical underwriting allowed. Traditional carriers must GI two standardized products until they meet enrollment caps, and HMOs must GI coverage one month each year. Elimination riders permitted. Credit for prior coverage required. 6-month look-back and 12-month exclusionary period limit on preexisting health conditions. Preexisting conditions may not be considered for HMO basic health service plans.
Oklahoma 73105	PPO	$238.25	$3500/$7000	100% coverage after the deductible.	Office visits, hospitalization and RX are subject to deductible. Additional $100 ER co-pay, and $50 outpatient co-pay and $3000 lifetime maximum for mental health services. Annual $3500/$7000 out-of-pocket maximum.	No rate caps and medical underwriting allowed, except for HMOs. (HMOs must community rate individual market coverage in Oklahoma and cannot look-back at preexisting conditions or impose exclusionary periods in this market; however, no HMOs offer individual market coverage in the state at this time.) High-risk pool serves the state medically uninsurable and HIPAA-eligible populations. Elimination riders allowed. Credit for prior coverage not required. Preexisting conditions may not be considered for HMO products. No look-back or exclusionary period limit for preexisting conditions for all other individual products.

State	Individual Market Health Insurance Options for Subject Family					Regulatory and Market Factors That May Impact Individual Market Health Insurance Pricing and Availability
	Plan Type	Monthly Premium	Annual In-Network Deductible (Individual /Family)	Coinsurance Rate	Additional Policy Benefits	
Oregon 97301	PPO	$249.00	$500 individual	80% coverage after the deductible.	Hospitalization, ER and maternity are subject to the deductible and coinsurance, with $100 ER co-pay (waived if admitted). Inpatient mental health subject to deductible and coinsurance and 30-day benefit limit, and chemical dependency subject to deductible and coinsurance, as well as a $4500 per consecutive 24-month period benefit limit. RX covered at 50% with a $10,000 benefit limit. Annual $4,000 out-of-pocket maximum.	Community rating with variances allowed based on geography and benefit design. Carriers must GI portability products to residents with 6 months of prior coverage. High-risk pool serves the state medically uninsurable and HIPAA-eligible populations. Elimination riders not permitted. Credit for prior coverage required. Preexisting conditions may not be considered for portability products. No look-back or exclusionary period limit for preexisting conditions for all other individual products.
Pennsylvania 17120	PPO	$251.77	$2500/$5000	100% coverage after the deductible.	Office visits, hospitalization and RX are subject to deductible and coinsurance. Additional $100 ER co-pay, and $50 outpatient co-pay and $3000 lifetime maximum for mental health services. Annual out-of-pocket maximum is $2500/$5000.	No rate caps and medical underwriting allowed. Various BCBS plans GIs some products to all consumers and serve as the GI option for HIPAA-eligible population. Elimination riders allowed, except for HIPAA-eligible individuals. Credit for prior coverage not required. Preexisting conditions may not be considered for HIPAA-eligibles. 60-month look-back and 36-month exclusionary period limit for preexisting conditions for other individual policies.

State	Individual Market Health Insurance Options for Subject Family					Regulatory and Market Factors That May Impact Individual Market Health Insurance Pricing and Availability
	Plan Type	Monthly Premium	Annual In-Network Deductible (Individual /Family)	Coinsurance Rate	Additional Policy Benefits	
Rhode Island 02903	PPO	$392.62	None	80% coverage after the deductible	Hospitalization, ER visits, and inpatient maternity and mental health subject to coinsurance. $500 per hospital admission co-payment.	No rate caps and medical underwriting allowed. All carriers must GI coverage to HIPAA-eligibles and individuals with 12-months of prior coverage. Elimination riders permitted except for GI plans. Credit for prior coverage not required except for GI plans. Preexisting conditions may not be considered for HIPAA-eligibles and those with 12 months of prior coverage. 36-month look-back and 12-month exclusionary period limit for preexisting conditions for other individual policies. State regulation of managed care entities makes it extremely difficult for carriers to offer individual market PPO products.
South Carolina 29201	PPO	$212.41	$2000/$4000	80% coverage after the deductible.	$35 office visit co-pay (maximum 2 visits per person, per year, then not covered). Well baby covered as per state mandates. Hospitalization and ER are subject to deductible and coinsurance. Additional $500 ER co-pay (waived if admitted). RX discount card. Annual out-of-pocket maximum is $3000 per person plus two deductibles per family per year.	No rate caps and medical underwriting allowed. High-risk pool serves the state medically uninsurable and HIPAA-eligible populations. Elimination riders allowed. Credit for prior coverage not required, except for HIPAA eligibles. 12-month look-back and exclusionary period limit for preexisting conditions for HMOs. Unlimited look-back and 24-month exclusionary period limit for preexisting conditions for other individual policies.

State	Individual Market Health Insurance Options for Subject Family					Regulatory and Market Factors That May Impact Individual Market Health Insurance Pricing and Availability
	Plan Type	Monthly Premium	Annual In-Network Deductible (Individual /Family)	Coinsurance Rate	Additional Policy Benefits	
South Dakota 57501	Managed Indemnity	$335.70	$2500/$7500	100% coverage after the deductible.	Non-preventive office visits, hospitalization and ER visits subject to deductible and coinsurance, with a separate $50 ER deductible (waived if admitted). RX discount card. Annual mental health benefit limits of $1000 outpatient/$2500 inpatient, and coverage is subject to coinsurance and limitations. $2500/$7500 annual out-of-pocket maximum.	Rates are subject to bands of plus or minus 30 percent of the base individual market rate. High-risk pool serves the state medically uninsurable and HIPAA-eligible populations. (Individuals must have at least 12-months of creditable coverage for risk-pool participation only if group coverage was lost through cancellation.) Elimination riders allowed. Credit for prior coverage required. 12-month look-back and exclusionary period limit on preexisting health conditions Geographical considerations may impact competition and prices.
Tennessee 37243	PPO	$210.43	$2500/$5000	100% coverage after the deductible.	Office visits, hospitalization and RX are subject to deductible and coinsurance. Additional $100 ER co-pay, and $50 outpatient co-pay and $3000 lifetime maximum for mental health services. Annual out-of-pocket maximum is $2500/$5000.	No rate caps and medical underwriting allowed. Tenncare serves the state's medically uninsurable population, but is closed at this time. Individual market serves as the GI option for HIPAA-eligible population. Elimination riders allowed, except for HIPAA-eligible individuals. Credit for prior coverage not required, except for HIPAA-eligibles. Preexisting conditions may not be considered for HIPAA-eligibles. No look-back or exclusionary period limit for preexisting conditions for other individual policies.

State	Individual Market Health Insurance Options for Subject Family					Regulatory and Market Factors That May Impact Individual Market Health Insurance Pricing and Availability
	Plan Type	Monthly Premium	Annual In-Network Deductible (Individual /Family)	Coinsurance Rate	Additional Policy Benefits	
Texas 78701	PPO	$253.00	$1500 individual (two member per family maximum)	75% coverage after the deductible.	$30 office visit co-pay for the first 4 visits per member per year with deductible waived; after 4 visits, 25% of negotiated fee. Hospitalization and ER subject to deductible and coinsurance. Mental health charges over $100 per day covered up to $3,000 per year maximum. Separate $150 RX deductible then $15/$25 co-pay. $3000/$6000 plus deductible annual out-of-pocket maximum.	No rate caps and medical underwriting allowed. High-risk pool serves the state medically uninsurable and HIPAA-eligible populations. Elimination riders allowed. Credit for 1-month or more prior coverage required. Preexisting conditions may not be considered for HMO products. 60-month look-back and 24-month exclusionary period limit for preexisting conditions for other individual policies.
Utah 84114	PPO	$240.00	$1000 individual	80% coverage after the deductible.	$20 office visit co-pay and $5/25%/50% RX co-pay. Separate $5000 maternity coverage deductible (not applied to out-of-pocket maximum), then 100% coverage. Hospitalization and ER visits subject to deductible and coinsurance, with $75 ER in-network co-pay. Mental health services subject to 50% coinsurance after the deductible plus benefit limits. $3500 annual out-of-pocket maximum, including deductible.	Rates are subject to rate bands of plus or minus 30 percent of the indexed individual market rate. Carriers must guarantee issue products to people that meet certain health criteria. High-risk pool serves the state medically uninsurable and HIPAA-eligible populations. Elimination riders allowed. Credit for prior coverage required. 6-month look-back and 12-month exclusionary period limit on preexisting health conditions. Carriers must GI coverage to certain HIPAA-eligibles who meet specified health criteria.
Vermont 05609	PPO	$578.94	$10000/$20000	100% coverage after the deductible	$30 office visit co-pay. All other benefits subject to deductible and coinsurance. $17000/$34000 out-of-pocket annual maximum.	All individual market coverage must be offered on a guarantee issue basis. 9-month look-back and a 12-month exclusionary period limit on preexisting health conditions. Carriers may only offer coverage on a community rated basis with adjustments limited to those approved by the state Insurance Commissioner. Currently variances of plus or minus 20 percent of the average group rate based on age and gender are allowed.

State	Individual Market Health Insurance Options for Subject Family					Regulatory and Market Factors That May Impact Individual Market Health Insurance Pricing and Availability
	Plan Type	Monthly Premium	Annual In-Network Deductible (Individual /Family)	Coinsurance Rate	Additional Policy Benefits	
Virginia 23219	PPO	$233.21	$1500/$3000	100% coverage after the deductible.	Office visits, hospitalization and RX are subject to deductible and coinsurance. Additional $100 ER co-pay, and $50 outpatient co-pay and $3000 lifetime maximum for mental health services. Annual out-of-pocket maximum is $1500/$3000.	Various BCBS plans GIs some products to all consumers. Individual market serves as the GI option for HIPAA-eligible population. Elimination riders allowed, except for HIPAA-eligible individuals. Credit for prior coverage not required, except for HIPAA-eligibles. Preexisting conditions may not be considered for HIPAA-eligibles. 12-month look-back and exclusionary period limit for preexisting conditions for other individual policies.
Washington 98504	PPO	$253.00	$1500/$4500	80% coverage after the deductible.	Office visits, hospitalization and ER visits are subject to deductible and coinsurance, $100 ER co-pay for in-network hospitals and a $150 co-pay for out-of-network. $4000/$12000 annual out-of-pocket limit.	Limited medical underwriting allowed. Carriers may only offer coverage on a modified community rated basis with adjustments limited to age, geography, wellness, family size and tenure in plan. Carriers must guarantee issue products to people that meet certain health criteria. In Elimination riders not permitted. Individual market serves as the GI option for HIPAA-eligible population. Credit for prior coverage is required. 6 month look-back and a 12-month exclusionary period limit on preexisting health conditions

State	Individual Market Health Insurance Options for Subject Family					Regulatory and Market Factors That May Impact Individual Market Health Insurance Pricing and Availability
	Plan Type	Monthly Premium	Annual In-Network Deductible (Individual /Family)	Coinsurance Rate	Additional Policy Benefits	
West Virginia 25305	PPO	$357.18	$5000/$10000	80% coverage after the deductible.	Office visits, hospitalization, and ER subject to the deductible and coinsurance. 50% coverage of RX, which is not subject to the deductible. Well-baby and well child visits covered at 100%. $6000/$12,000 annual out-of-pocket maximum.	Individual health insurance rates are subject to rate bands of plus or minus 30 percent of the base individual market rate. Individual market currently serves as the GI option for HIPAA-eligible population, but the state high-risk pool will assume that function during the summer of 2005. Elimination riders allowed, except for HIPAA-eligible individuals. Credit for prior coverage is not required except for HIPAA-eligibles. 12-month look-back and a 24-month exclusionary period limit on preexisting health conditions, except for HIPAA-eligibles.
Wisconsin 53707	PPO	$246.38	$1500/$3000	100% coverage the after deductible.	Office visits, hospitalization and RX are subject to deductible and coinsurance. Additional $100 ER co-pay, and $50 outpatient co-pay and $3000 lifetime maximum for mental health services. Annual out-of-pocket maximum is $1500/$3000.	No rate caps and medical underwriting allowed. High-risk pool serves the state medically uninsurable and HIPAA-eligible populations. Elimination riders allowed. Credit for prior coverage not required. 24-month exclusionary period limit for preexisting conditions.
Wyoming 82002	PPO	$239.65	$2100/$4200	100% after deductible	Office visits, RX, ER and hospitalization subject to deductible and coinsurance, with an additional $75 ER access fee (waived if admitted). $500 per year benefit for all wellness services. Mental health services $500 calendar year maximum $2,500 combined inpatient and outpatient, including inpatient chemical dependency with 50% coinsurance after deductible. Annual out-of-pocket maximum of $2000/$4000 plus deductible	No rate caps and medical underwriting allowed. High-risk pool serves the state medically uninsurable and HIPAA-eligible populations. Elimination riders allowed. Credit for prior coverage required. 6-month look-back and a 12-month exclusionary period limit on preexisting health conditions. Geographical considerations may impact competition and prices.

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Addendum C

National Association of Health Underwriters

State Level Individual and Small Group Market Health Insurance Reforms

February 2006

State	Individual Market Reforms						Small-Group Market Reforms[i]		
	Guarantee Issue	Rating Structure	Elimination Riders	Preexisting Conditions (Look-Back/ Exclusionary Period in Months)	Credit for Prior Coverage	Medically Uninsurable Individuals	Size[ii]	Preexisting Conditions (Look-Back/ Exclusionary Period in Months)	Rating Structure
Alabama	No	NRS	Yes	60/12	No	HRP[iii]	2-50	6/12	+/- 20%
Alaska	No	NRS	Yes	None	No	HRP	2-50	6/12	+/- 35%
Arizona	HIPAA[iv]	NRS	Yes[v]	None[vi]	No[vii]	None	2-50	6/12	+/- 60%
Arkansas	No	NRS	Yes	60-month Look-Back	No	HRP	2-50	6/12	+/- 25%
California	HIPAA[viii]	NRS	No	6/6 or 12/12[ix]	Yes	HRP/GI[x]	2-50	6/6	+/- 10%
Colorado	No	NRS	Yes	12/12	Yes	HRP	1-50[xi]	6/12	+/10% -25%
Connecticut	No	NRS	Yes	12/12	No	HRP	1-50[xii]	6/12	MCR[xiii]
Delaware	HIPAA[xiv]	NRS	Yes[xv]	None[xvi]	No[xvii]	None	1-50[xviii]	6/12	+/- 35%
Florida	HIPAA[xix]	NRS	Yes[xx]	24/24[xxi]	Yes	HRP[xxii]	1-50[xxiii]	6/12	MCR +/- 15%[xxiv]
Georgia	HIPAA[xxv]	NRS	Yes[xxvi]	24-month Exclusionary Period[xxvii]	No[xxviii]	None	2-50	6/12	+/- 25%
Hawaii	HIPAA[xxix]	NRS	Yes[xxx]	36-month Exclusionary	No[xxxii]	None	1-50[xxxiii]	None	NRS[xxxiv]

State	Individual Market Reforms						Small-Group Market Reforms[i]		
	Guarantee Issue	Rating Structure	Elimination Riders	Preexisting Conditions (Look-Back/ Exclusionary Period in Months)	Credit for Prior Coverage	Medically Uninsurable Individuals	Size[ii]	Preexisting Conditions (Look-Back/ Exclusionary Period in Months)	Rating Structure
				Period[xxxi]					
Idaho	GI[xxxv]	+/- 50%	No	6/12[xxxvi]	Yes	HRRP	2-50	6/12	+/- 50%
Illinois	No	NRS	Yes	12/24[xxxvii]	No	HRP	2-50	6/12	+/- 25%
Indiana	No	NRS	No	12/24	No	HRP	2-50	6/9	+/- 35%
Iowa	No	RB[xxxviii]	Yes	12/12 and 60/12[xxxix]	No[xl]	HRP	2-50	6/12	+/- 25%
Kansas	No	NRS	Yes	12/24	No	HRP	2-50	6/3	+/- 25%
Kentucky	No	+/- 35%	No	6/12	Yes	HRP	2-50	6/12	+/- 35%
Louisiana	No	NRS[xli]	Yes	12/12	Yes	HRP	3-35	6/12	+/- 35%
Maine	GI[xlii]	MCR[xliii]	No	12/6	Yes	GI	2-50	6/12	MCR[xliv]
Maryland	No	NRS	Yes	4/24	No	HRP	1-50[xlv]	0/0	MCR[xlvi]
Massachusetts	GI[xlvii]	MCR[xlviii]	No	6/6	Yes	GI	1-50[xlix]	6/6	MCR[l]
Michigan	GI[li]	CR/NRS[lii]	No	6/6 and 6/12[liii]	No	CLR[liv]	2-50[lv]	6/12	+/- 45%[lvi]
Minnesota	No	RB[lvii]	No	0[lviii]	Yes	HRP	2-50	6/12	+/- 25%
Mississippi	No	NRS	Yes	12/12	No	HRP	1-50[lix]	6/12	+/- 25%
Missouri	No	NRS	Yes[lx]	Unlimited/24[lxi]	No[lxii]	HRP	3-25	6/12	+/- 25%
Montana	No	NRS	Yes	36/12	Yes	HRP	2-50	6/12	+/- 25%
Nebraska	No	NRS	Yes	None	No	HRP	2-50	6/12	+/- 25%
Nevada	HIPAA[lxiii]	+/- 50%	Yes[lxiv]	None[lxv]	Yes	None	2-50	6/12	+/- 25%
New Hampshire	No	RB	Yes	3/9	Yes	HRP	2-50	6/12	MCR[lxvi]
New Jersey	GI[lxvii]	CR[lxviii]	No	6/12	Yes	GI	2-50	0/0 or 6/6[lxix]	MCR[lxx]
New Mexico	No	NRS	Yes	6/6	Yes	HRP	2-50	6/6	+/- 25%
New York	GI[lxxi]	MCR[lxxii]	No	6/12	Yes	GI	2-50	6/12	CR[lxxiii]
North Carolina	HIPAA[lxxiv]	NRS	Yes[lxxv]	12/12[lxxvi]	Yes	CLR[lxxvii]	1-50[lxxviii]	6/12	+/- 20%
North Dakota	No	RB	No	6/12	Yes	HRP	2-25	6/12	+/- 35%
Ohio	HIPAA[lxxix]	NRS[lxxx]	Yes	6/12	Yes	OE[lxxxi]	2-50	6/12	+/- 35%
Oklahoma	No	NRS[lxxxii]	Yes	None[lxxxiii]	No	HRP	2-50	6/12[lxxxiv]	+/- 25%

State	Individual Market Reforms						Small-Group Market Reforms[l]		
	Guarantee Issue	Rating Structure	Elimination Riders	Preexisting Conditions (Look-Back/ Exclusionary Period in Months)	Credit for Prior Coverage	Medically Uninsurable Individuals	Size[ll]	Preexisting Conditions (Look-Back/ Exclusionary Period in Months)	Rating Structure
Oregon	GI[lxxxv]	MCR[lxxxvi]	Yes	None[lxxxvii]	Yes	HRP	2-25	6/12	MCR[lxxxviii]
Pennsylvania	HIPAA[lxxxix]	NRS	Yes[xc]	60/36[xci]	No[xcii]	CLR[xciii]	2-50[xciv]	6/12	NRS[xcv]
Rhode Island	GI[xcvi]	NRS	Yes[xcvii]	36/12[xcviii]	No[xcix]	CLR[c]	1-50[ci]	6/12	+/- 10%
South Carolina	No	NRS	Yes	12/12 and unlimited/24[cii]	No	HRP	2-50	6/12	+/- 25%
South Dakota	No	+/- 30%	Yes	12/12	Yes	HRP	2-50	6/12	+/- 25%
Tennessee	HIPAA[ciii]	NRS	Yes[civ]	None[cv]	No[cvi]	None[cvii]	2-50	6/12	+/- 35%
Texas	No	NRS	Yes	60/24[cviii]	Yes[cix]	HRP	2-50	6/12	+/- 25%
Utah	GI[cx]	+/- 30%	Yes	6/12	No	HRP	2-50	6/12	+/- 30%
Vermont	GI[cxi]	MCR[cxii]	No	9/12	Yes	GI	2-50	6/12	MCR[cxiii]
Virginia	HIPAA[cxiv]	NRS	Yes[cxv]	12/12[cxvi]	No[cxvii]	CLR[cxviii]	2-50	6/12	NRS[cxix]
Washington	GI[cxx]	MCR[cxxi]	No	6/12	Yes	HRP	2-50	6/12	MCR[cxxii]
West Virginia	No	+/- 30%	Yes	12/24	No	HRP	2-50	6/12	+/- 30%
Wisconsin	No	NRS	Yes	24-month Exclusionary Period	No	HRP	2-50	6/12	+/- 30%
Wyoming	No	NRS	Yes	6/12	Yes	HRP	2-50	6/12	+/- 35%

Explanation of Abbreviations

Individual Market Reforms

Guarantee Issue—GI=Guarantee issue required, and HIPAA=People exercising their group-to-individual portability rights under the Federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) must be guaranteed issued products in the statewide individual market.

Rating Structure—NRS=No rating structure, Medical underwriting allowed without restrictions; HR=Rate bands; CR=Community rated; MCR=Modified community rated; and 1.5X=Rate bands of plus or minus the specified percentage of the indexed rate.

Marketable Uninsurable Individuals—HRP=High-risk health insurance pool; HRP/P=High-risk insurance pool; None=No mechanism for providing individual market access to medically uninsurable people; CLR=Carrier of last resort; OE=Open enrollment; and GI=Guarantee issue.

Small-Group Market Reforms

Rating Structure—1.5X=Rate bands of plus or minus the specified percentage of the indexed rate; NRS=No rating structure; CR=Community rated; and MCR=Modified community rated.

[i] In addition to the reforms noted, as per the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), all health insurance contracts for employer-groups of 2-50 employees must be issued on a guarantee-issue basis. All group insurance contracts must also be guarantee-renewable, unless there is non-payment of premium, the employer has committed fraud or intentional misrepresentation or the employer has not complied with the terms of the health insurance contract. In addition, according to HIPAA, credit for prior coverage is required as long as there is no more than a 63-day break in coverage.
[ii] Despite the group-size definition imposed by the state, as per federal law, all HIPAA protections apply to groups of 2-50.
[iii] Alabama's high-risk health insurance pool only serves the state's HIPAA-eligible population.
[iv] In Arizona, individuals exercising their federal group-to-individual health insurance rights provided by HIPAA can obtain guarantee-issue private individual health insurance coverage through any individual market health insurance carrier.
[v] Elimination riders aren't allowed for people exercising their group-to-individual portability rights under HIPAA.
[vi] Preexisting conditions cannot be considered for people exercising their group-to-individual portability rights under HIPAA.
[vii] Credit for prior coverage is required for people exercising their group-to-individual portability rights under HIPAA.
[viii] In California, all individual market carriers must guarantee issue their two most popular individual products to people who are exercising their group-to-individual portability rights provided by HIPAA. Carriers must also guarantee issue coverage to people who have spent two years in the state's high-risk health insurance pool.
[ix] In the California traditional individual health insurance market, there is a 12-month look-back and exclusionary period limit for pre-existing conditions for policies that cover one or two people. There is a 6-month look-back and exclusionary period limit for individual policies that cover three or more people.
[x] Carriers must guarantee issue coverage to people who have spent two years in the state's high-risk health insurance pool.
[xi] For employer groups-of-one employee, Colorado carriers must guarantee issue basic and standard small-group coverage during an annual open enrollment window to groups-of-one with involuntary loss of coverage only.
[xii] Connecticut regulations allow groups of one to apply for any plan however, following medical history review they may be offered the small group regulation guarantee issue product.
[xiii] Connecticut requires that small-group rates be based on a community rate with adjustments allowed for age, gender, geography, group size, family, and industry.
[xiv] In Delaware, individuals exercising their federal group-to-individual health insurance rights provided by HIPAA can obtain guarantee-issue private individual health insurance coverage through any individual market carrier offering coverage in the state.
[xv] Elimination riders aren't allowed for people exercising their group-to-individual portability rights under HIPAA.
[xvi] Preexisting conditions cannot be considered for people exercising their group-to-individual portability rights under HIPAA.
[xvii] Credit for prior coverage is required for people exercising their group-to-individual portability rights under HIPAA.
[xviii] In Delaware, carriers must guarantee-issue coverage to employer groups-of-one.
[xix] Currently in Florida, individuals exercising their federal group-to-individual health insurance rights provided by HIPAA can obtain guarantee-issue private individual health insurance coverage through either a conversion product, or through individual market carriers.
[xx] Elimination riders aren't allowed for people exercising their group-to-individual portability rights under HIPAA.
[xxi] Preexisting conditions cannot be considered for people exercising their group-to-individual portability rights under HIPAA.
[xxii] Florida's current high-risk pool, the Florida Comprehensive Health Association has been closed to new enrollees since 1991. As such, there is no mechanism currently in place to serve new medically uninsurable individuals who do not either have access to group coverage or guarantee issue rights provided under HIPAA. However, legislation was enacted in Florida in 2004 to create the Florida Health Insurance Plan, a new high-risk pool, which would combine the

existing pool with new enrollees. The development of the pool is contingent upon the creation of a funding mechanism. A legislative effort is currently underway to create a funding mechanism for the pool, so that it can become operational and accept new enrollees.

[xxiii] In Florida, carriers must guarantee issue certain small-group products to groups-of-one during annual open enrollment periods.

[xxiv] In the small group market in Florida there are rate bands of +/-15% of the indexed rate depending on the health of the group. Groups over 10 employees may use a group medical questionnaire. Groups of fewer than 10 employees must answer individual medical questionnaires. Small employer health insurance carriers may only use the following rating factors: geographic area and number of employees, as well as health of the group. Renewals are capped at 15% plus trend.

[xxv] In Georgia, individuals exercising their federal group-to-individual health insurance rights provided by HIPAA can obtain guarantee-issue private individual health insurance coverage through either a conversion product, or through individual market carriers on an assignment basis.

[xxvi] Elimination riders aren't allowed for people exercising their group-to-individual portability rights under HIPAA.

[xxvii] Preexisting conditions cannot be considered for people exercising their group-to-individual portability rights under HIPAA.

[xxviii] Credit for prior coverage is required for people exercising their group-to-individual portability rights under HIPAA.

[xxix] In Hawaii, individuals exercising their federal group-to-individual health insurance rights provided by HIPAA can obtain guarantee-issue private individual health insurance coverage through any individual market health insurance carrier.

[xxx] Elimination riders aren't allowed for people exercising their group-to-individual portability rights under HIPAA.

[xxxi] Preexisting conditions cannot be considered for people exercising their group-to-individual portability rights under HIPAA.

[xxxii] Credit for prior coverage is required for people exercising their group-to-individual portability rights under HIPAA.

[xxxiii] Hawaii does not have a statute that defines the size of their small group market. Most carriers define it as 1-50; however, some use the definition of 1-100. Individuals who attempt to obtain guarantee-issue coverage as a business group-of-one must satisfy criteria set by the carrier.

[xxxiv] Coverage in the Hawaii small group market may be medically underwritten. The state does not have specified rate requirements, except that all rates must be reasonable for the coverage provided, and effective 1/1/2003, all rates must have prior approval by the state Department of Insurance.

[xxxv] Idaho individual health insurance carriers must guarantee issue at least three products (basic, standard and catastrophic) to all individual market consumers with 12 months of creditable coverage, including all HIPAA-eligible individuals.

[xxxvi] Preexisting conditions may not be considered for standardized policies.

[xxxvii] For traditional individual health insurance policies in Illinois, there is a 12-month look back period during first two years of coverage. If the condition is determined to be preexisting a 24-month exclusionary period is allowed.

[xxxviii] Carriers are subject to rating restrictions based on the pricing for their different blocks of business. The rate differential between the two policy forms must be no more than 2.028 to 1 at each age, (i.e., the composite effect of 30%, and 20%). Subsequent rate changes must be within 15% of each other.

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[xl] Credit for prior coverage is required for HIPAA-eligibles and standardized policies.

[xli] There are no rate caps in the individual health insurance market in Louisiana, as statutory rate bands are not enforced.

[xlii] In Maine, all major medical individual health insurance products must be sold on a guarantee issue basis to all consumers, including all HIPAA-eligible individuals.

[xliii] In Maine, the individual market is rated on a modified community basis. Adjustments of plus or minus 20 percent of the community rate are only allowed for age, occupation, and geography. A separate adjustment can be made for smoker status.

[xliv] In Maine, small group health plan rates are determined on a modified community basis. Rates can only be adjusted by plus or minus 20% from the standard community rate for the following factors: age, geography, occupation, and smoking status. The use of medical underwriting is prohibited.
[xlv] In Maryland, carriers must guarantee issue a standardized coverage plan to self-employed individuals during an annual open enrollment period.
[xlvi] In Maryland, small group health insurance coverage premiums must be community rated with up to 40 percent plus or minus variations allowed for age and geography.
[xlvii] All Massachusetts individual market health insurance carriers must sell at least three products to all consumers on a guarantee issue basis, including all HIPAA-eligible individuals.
[xlviii] Carries may adjust rates on a modified community rated basis. Adjustments are limited to age, geography and benefit level on a 2:1 basis.
[xlix] In Massachusetts, carriers must guarantee-issue coverage to business groups-of-one.
[l] In Massachusetts, small group health insurance premiums must be based on a community rate, with adjustments allowed for age, industry, group size, geography, family composition, participation rate, wellness program participation, and participation in the small employer reinsurance plan.
[li] Blue Cross Blue Shield of Michigan must offer all products to all residents on a guarantee issue basis, and HMOs in the state must offer guarantee issue coverage to residents during annual open enrollment periods.
[lii] Blue Cross Blue Shield of Michigan must community rate products in the individual market, but other carriers have no rate restrictions.
[liii] There is a 6-month look-back and exclusionary period limit on preexisting health conditions for Blue Cross Blue Shield of Michigan and HMOs. All other individual market carriers are subject to a 6-month look-back and a 12-month exclusionary period limit on preexisting health conditions.
[liv] Blue Cross Blue Shield of Michigan is required by statute to serve as the carrier of last resort for people seeking coverage in the individual market through a year-round open enrollment for specified products. Also, HMOs in Michigan are required to offer individual coverage with a 30-day open enrollment period for all individuals annually.
[lv] In Michigan, commercial carriers and Blue Cross Blue Shield of Michigan may impose an open enrollment period for sole proprietors and impose a 6 month look-back and exclusionary exclusion period for preexisting conditions.
[lvi] Blue Cross Blue Shield of Michigan is allowed to impose a 35 percent variation from the geographic rate for small groups.
[lvii] Minnesota individual health insurance market rates are subject to bands of plus or minus 25 percent of the base individual market rate for health status, plus or minus 50 percent for age and plus or minus 20 percent for geography.
[lviii] There is no exclusionary period allowed for preexisting health conditions for people with creditable coverage in Minnesota.
[lix] In Mississippi, carriers must guarantee-issue coverage to business groups-of-one.
[lx] Elimination riders aren't allowed for people exercising their group-to-individual portability rights under HIPAA.
[lxi] Preexisting conditions cannot be considered for people exercising their group-to-individual portability rights under HIPAA.
[lxii] Credit for prior coverage is required for people exercising their group-to-individual portability rights under HIPAA.
[lxiii] In Nevada, individuals exercising their federal group-to-individual health insurance rights provided by HIPAA can obtain guarantee-issue private individual health insurance coverage in the form of a basic or standardized plan through any individual market carrier.
[lxiv] Elimination riders permitted except for HIPAA-eligibles and in the Nevada basic and standard plans.
[lxv] Preexisting conditions cannot be considered for people exercising their group-to-individual portability rights under HIPAA.
[lxvi] In New Hampshire, small group health insurance premiums must be based on a community rate, with adjustments allowed for age, family composition, group size and industry classification when determining rates, and the use of health status, claims experience, duration of coverage, geographic location and other characteristics is prohibited.

[lxvii] All New Jersey individual market health insurance carriers must guarantee issue five standardized products to all consumers, including HIPAA-eligible individuals.
[lxviii] Traditional individual coverage must be purely community-rated. Carriers may also offer a basic and essential plan, which may have 3.5:1 variations for age, gender and geography.
[lxix] In New Jersey, new groups sized 2-5 are subject to a 6-month look-back/6-month preexisting condition exclusion period, but other small groups are not subject to an exclusion period. Late enrollees in groups of 2-50 may also be subject to a 6-month preexisting condition waiting period.
[lxx] In New Jersey, small-group premiums are based on a modified community rate, and carriers may consider only the age, gender and family status of eligible employees, and the location of the employer in determining the premium for the group. Carriers may not consider any other factor, including health status or prior claims history of eligible employees or the type of business. Carriers are required to limit the range of premiums from the highest risk group and the lowest risk group to a 2:1 basis.
[lxxi] In New York, all carriers must guarantee issue all individual health insurance products to all consumers, including HIPAA-eligible individuals.
[lxxii] Coverage must be community-rated with adjustments limited to family composition and geographic regions.
[lxxiii] In New York, small group health insurance premiums are subject to pure community rating.
[lxxiv] In North Carolina, individuals exercising their federal group-to-individual health insurance rights provided by HIPAA can obtain guarantee-issue private individual health insurance coverage through any individual market carrier. In addition, Blue Cross/Blue Shield of North Carolina voluntarily sells certain products on a guarantee-issue basis to all consumers.
[lxxv] Elimination riders aren't allowed for people exercising their group-to-individual portability rights under HIPAA.
[lxxvi] Preexisting conditions cannot be considered for people exercising their group-to-individual portability rights under HIPAA.
[lxxvii] Blue Cross Blue Shield of North Carolina voluntarily serves as the carrier of last resort for people seeking coverage in the individual market through a year-round open enrollment for specified products.
[lxxviii] In North Carolina, carriers must guarantee issue basic and standard plans to business groups-of-one.
[lxxix] Traditional Ohio individual market carriers must guarantee issue two standardized products to individuals exercising their group-to-individual portability rights provided by HIPAA until they meet enrollment caps, and HMOs must guarantee issue coverage one month each year to HIPAA eligible individuals.
[lxxx] Standardized plans are subject to rate caps.
[lxxxi] In Ohio, HMOs and insurers must hold annual open enrollment periods during which they must offer two specified products to all individuals until they meet specified statutory enrollment caps.
[lxxxii] Individual market HMOs are subject to rate caps; however, no HMOs offer individual market coverage in the state at this time.
[lxxxiii] Preexisting conditions may not be considered for HMO products in the Oklahoma individual health insurance market, however, no HMOs offer individual market coverage in the state at this time.
[lxxxiv] In Oklahoma, HMOs cannot consider, look-back at or issue exclusions for preexisting conditions. All other group health insurance carriers can impose a 6-month look-back/12-month exclusionary period for preexisting conditions on enrollees that do not have prior creditable coverage.
[lxxxv] In Oregon, all individual market carriers must guarantee issue portability products to residents with six months of prior coverage.
[lxxxvi] Oregon individual carriers must use community rating with variances allowed based on geography and benefit design.
[lxxxvii] Preexisting conditions may not be considered for portability products in Oregon's individual health insurance market.
[lxxxviii] Small group health insurance premiums in Oregon must be based on a modified community rate. For groups of 2-25 employees, rating is based on family mix, member age, and geographic location of the employer. All carrier rates must have no more than a .43 difference in rates between the highest age and lowest

age band. For groups of 26-50 employees, rates also must be based on family mix, member age, gender and geographic location of the employer, but there are no age band requirements.

[lxxxix] In Pennsylvania, individuals exercising their federal group-to-individual health insurance rights provided by HIPAA can obtain guarantee issue private individual health insurance coverage through the various Blue Cross/Blue Shield plans serving as the state's carriers-of-last resort. The various Blue Cross/Blue Shield plans also offer a medical-only product to all consumers on a guarantee-issue basis.

[xc] Elimination riders aren't allowed for people exercising their group-to-individual portability rights under HIPAA.

[xci] Preexisting conditions cannot be considered for people exercising their group-to-individual portability rights under HIPAA.

[xcii] Credit for prior coverage is required for people exercising their group-to-individual portability rights under HIPAA.

[xciii] The various Blue Cross/Blue Shield plans operating in the state voluntarily serve as the carriers-of-last-resort for people seeking coverage in the individual market through a year-round open enrollment for specified products.

[xciv] Pennsylvania does not have a specific statute or regulation that defines the size of a small employer for the purposes of providing health insurance coverage. Most Pennsylvania insurance carriers define a small group as 2-50 employees.

[xcv] In the small group health insurance market in Pennsylvania, medical underwriting is allowed without restriction with rate variations allowed up to 300 percent of the base rate. Some Blue Cross/Blue Shield carriers community rate or use a modified community rate voluntarily.

[xcvi] All carriers must guarantee issue coverage to all individuals with at least 12 months of prior coverage. Blue Cross Blue Shield of Rhode Island voluntarily offers an individual health insurance product to all consumers on a guarantee issue basis. HIPAA-eligible individuals can obtain guarantee-issue private individual health insurance coverage through any individual market health insurance carrier.

[xcvii] Elimination riders aren't allowed for people exercising their group-to-individual portability rights under HIPAA or for the guarantee issue products.

[xcviii] Preexisting conditions cannot be considered for people exercising their group-to-individual portability rights under HIPAA or those with 12 months of prior coverage.

[xcix] Credit for prior coverage is required for people exercising their group-to-individual portability rights under HIPAA and in the guarantee issue plans.

[c] Blue Cross Blue Shield of Rhode Island voluntarily serves as the carrier of last resort for people seeking coverage in the individual market through a limited annual open enrollment period.

[ci] In Rhode Island, carriers must guarantee issue coverage to business groups-of-one.

[cii] There is a 12-month look-back and exclusionary period limit for preexisting conditions for HMOs in South Carolina's individual health insurance market. There is an unlimited look-back and 24-month exclusionary period limit for preexisting conditions for other individual policies.

[ciii] In Tennessee, individuals exercising their federal group-to-individual health insurance rights provided by HIPAA can obtain guarantee-issue private individual health insurance coverage through any individual market health insurance carrier.

[civ] Elimination riders aren't allowed for people exercising their group-to-individual portability rights under HIPAA.

[cv] Preexisting conditions cannot be considered for people exercising their group-to-individual portability rights under HIPAA.

[cvi] Credit for prior coverage is required for people exercising their group-to-individual portability rights under HIPAA.

[cvii] Some medically uninsurable individuals in Tennessee are still eligible for the state's scaled-back TennCare program.

[cviii] Preexisting conditions may not be considered for HMO products in the Texas individual market.

[cix] Credit for one month or more prior coverage is required.

[cx] In Utah, individual market carriers must guarantee issue products to people that meet certain health criteria. Individuals who do not meet these criteria can obtain guarantee-issue private individual health insurance coverage through the state's high risk pool.